NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of sacrocolpopexy using mesh to repair vaginal vault prolapse

The vaginal vault is a structure formed at the top of the vaginal canal after surgery to remove the womb and the cervix. Vaginal vault prolapse happens when the upper part of the vagina slips down from its usual position. Sacrocolpopexy is an operation that aims to support for the pelvic organs in their natural position. This is achieved by attaching a piece of mesh, usually from the top and back of the vagina, to a ligament of the lower back bone.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in June 2016.

Procedure name

- Sacrocolpopexy using mesh for vaginal vault prolapse repair

Specialist societies

- British Association of Urological Surgeons (BAUS)
- Royal College of Obstetricians and Gynaecologists (RCOG)
- British Society of Urogynaecology (BSUG)

Description

Indications and current treatment

Vaginal vault prolapse is when the upper part of the vagina descends from its usual position, sometimes out through the vaginal opening. It is more common after hysterectomy.

Vaginal vault prolapse may occur on its own or together with a cystocele (when the bladder sags into the vagina), rectocele (when the front wall of the rectum bulges into the lower wall of the vagina) or enterocele (when the intestine bulges into the upper wall of the vagina).

It can affect quality of life by causing symptoms of pressure and discomfort, and by its effect on urinary, bowel and sexual function.

Treatment options for vaginal vault prolapse depend on the severity of the symptoms. Treatment is rarely indicated if there are no symptoms. Mild-to-moderate prolapse may be treated by conservative measures such as pelvic-floor muscle training, electrical stimulation and biofeedback. Topical oestrogens and mechanical measures such as pessaries may also be used.

Surgery may be needed when the prolapse is severe. A number of different surgical procedures are available for repairing vaginal vault prolapse using vaginal or abdominal (open, laparoscopic or robotic) approaches. Some procedures involve the use of mesh, with the aim of providing additional support.

What the procedure involves

Sacrocolpopexy using mesh to repair vaginal vault prolapse is done with the patient under general anaesthesia, using an open or laparoscopic abdominal approach. Mesh is attached to the longitudinal ligament of the sacrum, most often at the level of the sacral promontory. The mesh is then attached to the apex of the vagina and sometimes to the anterior or posterior vaginal wall.

The procedure can be combined with surgery for stress urinary incontinence, such as colposuspension or sub-urethral sling placement.

Several different types of meshes or grafts have been used for this procedure, including synthetic meshes (polypropylene), allografts (cadaveric fascia lata) and xenografts (porcine dermis or small intestinal mucosa).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to sacrocolpopexy using mesh for vaginal vault prolapse repair. The following databases were searched, covering the period from 1July 2007 to 6 June 2016: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature. Non-randomised studies with samples size smaller than 100 patients or a follow-up inferior to 24 months were also excluded.
Patient	Female patients with vaginal prolapse.
Intervention/test	Open, laparoscopic or robotic sacrocolpopexy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on data from about 4,982 patients included in 3 systematic reviews and meta-analysis[1-3], 2 randomised control trials[4,5] and 3 prospective case series[6-8].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on sacrocolpopexy using mesh for vaginal vault prolapse repair

Study 1 Maher C (2013)

Details

Study type	**Systematic review and meta-analysis**
Country	UK.
Recruitment period	Most recent search date was 20 August 2012
Study population and number	n=**5,954 women from 56 RCTs** 9 studies evaluated surgeries for upper vaginal prolapse (uterine or vault) (**n=2039**): - 3 trials compared SCP versus vaginal sacrospinous colpopexy - 1 trial compared SCP with high vaginal uterosacral colpopexy - 1 study compared abdominal SCP with LSC - 1 RCT compared LSC with total vaginal polypropylene mesh kit (TMV) - 1 trial compared LSC with RSC - 2 trials compared apical prolapse repair with continence surgery versus prolapse repair with no continence surgery - 1 trial compared SCP using absorbable cadaveric fascia graft with non-absorbable mesh
Age and sex	Adult women.
Patient selection criteria	RCTs or quasi-randomised controlled clinical studies involving any type of abdominal or vaginal surgery for POP
Technique	For the purpose of the synthesis outcomes were selected if reporting a comparison between SCP and another POP intervention, SCP and LSC, SCp and RASC or comparing different types of mesh used in SCP.
Follow-up	NR.
Conflict of interest/source of funding	One of the authors of the systematic review is also the author of 2 studies included in the synthesis.

Analysis

Follow-up issues: Loss to follow-up ranged from 0% to 53%

Study design issues:
- Data extraction was done by 2 review authors and results compared to ensure accuracy.
- In 1 of the trials 4 women received the opposite treatment to their randomised allocation (mesh instead of fascia) and were analysed in the mesh group which has compromised the randomisation process. Intention-to-treat analysis not used.
- In 1 study comparing open and laparoscopic sacrocolpopexy, women who were unfit for sacrocolpopexy were excluded. No CONSORT statement, intention-to-treat analysis or blinding status of the assessors was provided and continuous data were reported without standard deviations.
- 38 studies were excluded from the systematic review.
- Women and surgeons couldn't be blinded to the procedure when different interventions were being compared.
- Four of the studies evaluating 1 type of upper vaginal prolapse surgery compared with another where updates of previously included trials.

Study population issues: There was some clinical heterogeneity between the patients in 2 of the trials comparing sacrocolpopexy with sacrospinous hysteropexy as some women had hysterectomy in addition to a prolapse procedure. There was no description of exclusion criteria in 1 study comparing open sacral colpopexy and high uterosacral colpopexy.

Other issues: This paper is an updated systematic review and meta-analysis of a paper published in 2011.
Some studies included in this systematic review and meta-analysis overlap with other papers in Table 2:

- 5 studies (Maher 2004, Benson 1996, Roovers 2004, Lo 1998 and Rondini 2011) overlap with Siddiqui 2015.
- One study by Paraiso 2011 was also included by Serati 2014.

Key efficacy and safety findings

Efficacy	Safety
n=**5,954 women from 56 RCTs** **Subjective failure** SCP 10% (9/84) versus VSC 21%(18/85): RR: 0.53; 95%CI, 0.25-1.09 (n=169), I^2=0%, p=0.65. **Patient satisfaction** • Women unsatisfied with surgery SCP versus VSC: RR: 0.82; 95%CI, 0.32-2.06 (n=89) • PGP-I SCP (n=24) versus LSC (n=23): RR: 0.96, 95%CI, 0.65-1.42 • VAS scale of 0 to 100 (maximum) LSC (53) versus TVM (55): MD: 8.10, 95%CI, 0.2 -16.0 **Objective failure** • Women failing to improve to Stage 2* or better SCP 6%(3/52) versus VSC 20%(13/66): RR: 0.29; 95CI, 0.09-0.97 LSC 23%(12/53) versus TVM 58%(32/55) RR 0.39, 95%CI, 0.23-0.67 at 2 years follow-up. • Lower rate of recurrent vault prolapse (n=169) SCP 4%(3/84) versus VSC 15%(13/85): RR 0.23; 95%CI, 0.07-0.77, I^2=0%, p=0.018. • Any pelvic organ prolapse (n=88) SCP 24%(11/46) versus VSC 31%(13/42): RR 0.77; 95%CI, 0.39-1.53 • Less post-operative SUI (n=128) SCP 30%(14/47) versus VSC 35%(28/81): RR: 0.55, 95%CI, 0.32-0.95 • Less post-operative dyspareunia (n=106) SCP 16%(7/45) versus VSC 36%(22/61): RR: 0.39, 95%CI, 0.18-0.86. • POP-Q measurements o Point C less than 1cm (recurrence in the anterior or posterior compartments) SCP versus LSC: MD: 0.0, p=0.71, 95%CI, -0.74 to 0.74 LSC (53) versus TVM (55): MD: 1.39, 95%CI, 0.39 to 2.39 at 2 years follow-up. SCP (n=181) versus SCP+ colposuspension (n=177): RR: 0.41, 95%CI, 0.13-0.69, I^2=46%, p=0.0046 o Point Ba LSC (53) versus TVM (55): MD: 0.7, 95%CI, 0.36 to 1.04, p≤0.0001 o Point Bp LSC (53) versus TVM (55): MD: 0.7, 95%CI, 0.37 to 1.03, p≤0.0001.	**Mesh exposure** Procedures comparison LSC 2%(1/53) versus TVM 13%(7/55): RR: 0.15, 95%CI, 0.02-1.16 Type of graft comparison Cadaveric fascia lata graft 32%(14/44) versus permanent polypropylene mesh 9%(4/45): RR: 3.58 95%CI, 1.28-10.03
Abbreviations used: Ba, most distal position of the remaining upper anterior vaginal wall; Bp, most distal portion of the remaining upper posterior vaginal wall; C, most distal edge of cervix or vaginal cuff scar, HUSLS, high vaginal uterosacral colpopexy; LSC, laparoscopic sacrocolpopexy; MD, mean difference; POP, pelvic organ prolapse; PGI-I, Patient global impression improvement; POP-Q, pelvic organ prolapse quantification system; RR, risk ratio, SCP, sacrocolpopexy; SUI, Stress urinary incontinence; VAS, visual analogue scale; VSC, vaginal sacrospinous colpopexy; TVM, total vaginal polypropylene mesh kit;	

*Stage 2 prolapse – Leading edge descending to within 1 cm of the hymen.

Study 2 Siddiqui NY (2015)

Details

Study type	**Systematic review and meta-analysis**
Country	USA
Recruitment period	Studies published until 4 June 2012
Study population and number	**n=1,176** (approximately) 13 Studies included in the evaluating anatomic success : • 5 RCTs • 1 prospective study • 7 retrospective non-randomised cohort studies Studies included in the analysis of adverse events: • 13 studies above • 5 short-term comparative studies • 61 non-comparative studies
Age and sex	Adult women. Mean ages not reported.
Patient selection criteria	Women with any degree of apical prolapse having surgical treatment were included; The intervention of interest was sacrocolpopexy (abdominal, laparoscopic or robotic) using mesh.
Technique	Comparative studies with a follow-up greater than 6 months were included in the primary analyses. Non-comparative studies and shorter follow-up ones were included in the analysis of adverse events.
Follow-up	**RCTs - 1 to 2.5 years** **Non-randomised comparative studies - 6 months to 8.3 years**
Conflict of interest/source of funding	The author is supported by award number K12-DK100024 from the national Institute of Diabetes and Digestive and Kidney Disease. This study was done by the Society of Gynaecologic Surgeons and Systematic Review groups. No conflicts of Interest declared.

Analysis
Follow-up issues: Shorter follow-up studies were included for adverse events analysis.
Study design issues:

- Meta-analyses were performed when there were at least 3 studies reporting the same outcome.
- Due to the large number of case series, only studies that included a minimum of 200 patients were used in the analysis of adverse events.
- Abstracts were screened by 2 independent reviewers. Disagreements were resolved by consensus or the judgement of a third reviewer.
- Studies methodological quality was assessed by using the Agency for Healthcare Research and Quality three category system (A – God, B – Fair, C – Poor). Individual Outcomes were graded according to the GRADE system.
- The author mentions the use of PRISMA statement.
- Quality of evidence:
    - Anatomic outcomes after sacrocolpopexy – moderate quality
    - Difference in reoperation between sacrocolpopexy and native tissue vaginal repairs - very low quality.
    - Evidence about bowel and bladder symptoms - insufficient.
    - Post-operative sexual function – low quality.
- One RCT was only published as an abstract and wasn't included in the meta-analysis.
- 38 studies were excluded from the systematic review.

Study population issues: The intervention of interest is sacrocolpopexy but the analysis included some patients that had hysteropexy and cervicopexy procedures. Percentages reported by the author in outcomes not included in the synthesis. Author doesn't report overall subgroups' percentages.
For mesh sacrocolpopexy, the majority of comparative studies used an open abdominal approach. Overall results from robot-assisted sacrocolpopexy (RASC) or laparoscopic sacrocolpopexy (LSC) may differ from this analysis' reported outcomes. The number of participants recruited by the 61 non-comparative studies included in the analysis of adverse events was not reported by the author.

Other issues: Five studies (Maher 2004, Benson 1996, Roovers 2004, Lo 1998 and Rondini 2011) included in this systematic review and meta-analysis were also included in Maher 2013, Study 1 in Table 2.

Key efficacy and safety findings

Efficacy	Safety

Objective failure

Stage 2 or greater in POP-Q

- Mesh SCP (132/177) versus native tissue vaginal repair (119/192): pooled OR 2.04; 95% CI, 1.12-3.72, I^2=31%, Phet=0.23.[a]
- LSC 17%(10/60) versus SSLF 0/51:p<0.01[b]

Studies were too heterogeneous to pool and obtain results regarding sexual function, bowel and bladder function.

Reoperation

SCP 13%(6/46) versus SSLF 16%(7/43), p=0.67[c]

Adverse events in 18 comparative studies

Adverse event	Studies**	No. Studies (excluded)	OR (95%CI)	Events	
				Mesh	Native tissue
Dindo 1					
Ileus/SBO	All	7 (-1)	9.45 (3.39-26.4) *	2% (16/814)	<1% (2/780)
	RCTs	2	9.55 (1.31-69.4)	5% (4/86)	0/108
Nerve Injury*[a]	All	5	0.61 (0.18-2.05)	1% (4/514)	1% (7/743)
	RCTs	2	8.32 (1.15-60.3)	5% (4/75)	0/83
Dyspareunia*[b]	All	5	0.42 (0.25-0.72) *	5% (23/445)	12% (46/384)
	RCTs	3	0.14 (0.06-0.33)	1% (1/107)	25% (27/106)
Dindo 2					
Bleeding*[c]	All	12 (-1)	1.00 (0.63-1.59)	3% (43/1317)	2% (37/1863)
	RCTs	3	1.02 (0.20-5.14)	2% (3/123)	2% (3/128)
DVT/PE	All	4 (-2)	1.36 (0.14-13.7)	<1% (2/569)	<1% (1/599)
	RCTs	0	-	-	-
Infection*[d]	All	7 (-1)	2.01 (0.91-4.45)	3% (17/676)	1% (9/617)
	RCTs	4	1.98 (0.60-6.55)	4% (7/171)	2% (4/193)
Dindo 3a					
Mesh/suture complication	All	7	3.26 (1.62-6.56) *	4% (28/650)	1% (6/537)
	RCTs	3	7.72 (1.08-55.2)	3% (4/122)	0/131
Dindo 3b					
Reoperation	All	7	0.76 (0.28-1.09)	7% (46/615)	10% (51/511)
	RCTs	4	0.97 (0.33-2.88)	16% (25/153)	17% (29/168)
Urinary tract injury	All	8 (-2)	1.68 (0.79-3.55)	2% (20/1068)	1% (9/1108)
	RCTs	3	1.65 (0.28-9.65)	2% (3/134)	1% (2/154)
Bowel injury	All	10(-2)	0.91 (0.35-2.37)	1% (8/1219)	1% (10/1574)
	RCTs	3	0.57 (0.06-5.54)	1% (1/130)	1% (2/147)
Dindo 4a					
ICU admission*[e]	All	4 (-2)	4.64 (0.42-50.6)	1% (3/561)	0/506
	RCTs	0	-	-	-
Dindo 5					
Death	All	4 (-3)	0.14 (0.003-6.97)	0/503	<1% (1/582)
	RCTs	1	0.14 (0.003-6.97)	0/47	2% (1/47)

*p<0.001

**Studies excluded from the meta-analysis, no events occurred in either group.

*[a] Or neuropathy

*[b] Or sexual dysfunction

*[c] Or haematoma or transfusion

*[d] Would or pelvic/cuff infection

*[e] Cardiovascular or pulmonary event

Adverse events in comparative and non-comparative studies

AE	Mesh sacrocolpopexy	Native tissue vaginal repair	P

	% (95CI)	Range	No. studies	AE	% (95CI)	Range	No. studies	AE	
Dindo 1									
Ileus/SBO	2.7 (1.7-3.9)	0-12	24	3% (137/4168)	0.2 (0.1-0.6)	0-0.5	11	<1% (3/1449)	<0.01
Nerve Injury*[a]	1.3 (0-3.7)	0-8.2	12	4% (96/2601)	4.5 (1.8-8.2)	0-46	16	5% (147/2813)	0.1
Dyspareunia*[b]	7.3 (3-13)	0-39	15	12% (371/2986)	9.9 (5.2-16)	0-58	17	9% (200/2180)	0.48
Dindo 2									
Bleeding*[c]	1.5 (1-2.1)	0-12	34	2% (128/6555)	2.9 (1.5-4.8)	0-20	34	5% (367/7044)	0.05
DVT/PE	0.6 (0.2-1.2)	0-2.8	15	1% (46/4579)	0.1 (0-0.3)	0-0.83	15	<1% (8/4114)	0.03
Infection*[d]	2.2 (1.2-3.4)	0-7.9	25	2% (114/5519)	1.8 (0-8.3)	0-55	19	12% (558/4743)	0.6
Dindo 3a									
Mesh/suture complication	4.2 (3.2-5.4)	0-18	40	4% (348/7831)	0.4 (0-1.7)	0-7.8	11	1% (13/1169)	<0.001
Dindo 3b									
Reoperation	5.4 (3.8-7.1)	0.32-25	31	5% (367/7218)	3.7 (2.0-5.9)	0-33	22	3% (114/3872)	0.28
Urinary tract injury	1.5 (0.8-2.3)	0-9.8	34	2% (113/6894)	0.6 (0.2-1.1)	0-3.5	25	1% (46/5111)	0.05
Bowel injury	0.3 (0.1-0.6)	0-4.7	31	1% (37/6642)	0.6 (0.2-1)	0-3.8	28	1% (47/5744)	0.33
Dindo 4a									
ICU admission*[e]	2.1 (0-6.3)	0-24	14	6% (281/4233)	0.5 (0.1-1.2)	0-4.5	13	1% (27/3532)	0.11
Dindo 5									
Death	0.2 (0.1-0.4)	0-2.4	13	<1% (6/3343)	0.1 (0-0.4)	0-2.1	14	<1% (12/4105)	0.61

Abbreviations used: AE, adverse event; CI, confidence interval; DVT, deep vein thrombosis; GRADE, grades for recommendation, assessment, development and evaluation; ICU, intensive care unit; I^2, percentage of total variation across studies due to heterogeneity; LSC, laparoscopic sacrocolpopexy; PE, pulmonary embolism; POP-Q, pelvic organ prolapse quantification system; PRISMA, preferred reported items for systematic reviews; RCT, randomised control trial; RASC, robot-assisted sacrocolpopexy; SBO, small bowel obstruction; SCP, sacrocolpopexy; NR, not reported; Phet, P value for statistical heterogeneity; SSLF, sacrospinous ligament fixation.

[a]Thee of the four RCTs included in the meta-analysis reported anatomic success for individual compartments. Meta-analysis pools all compartments. Study quality: B, C, A, B.

[b]One cohort study reported similar anterior and apical outcomes but more posterior wall recurrences after SCP compared to SSLF.

[c]There were highly inconsistent results from RCTs regarding reoperations rates.

[d]The highest quality study reported no significant difference in all-cause reoperation. Adverse events were classified in Dindo categories: Grade II – mesh extrusion treatable with local estrogen, Grade IIIa – excision with none or local anaesthesia; Grade IIIb – excision with general anaesthesia. The author defined all mesh extrusions or erosions as a Dindo grade III

Study 3 Serati M (2014)

Details

Study type	**Systematic review and meta-analysis**
Country	Italy
Recruitment period	Databased searched systematically for records published between 2000 to 2013, included papers published between 2006 and 2013
Study population and number	n=**1,488 patients from 27 studies** - **17 single arm studies** - **10 comparative studies (4 RASC versus SCP and 6 RASC versus LSC)**
Age and sex	Adult women. Mean age not reported.
Patient selection criteria	All English language original reports describing more than 10 sacrocolpopexy procedures performed using robotic assistance.
Technique	RASC was compared with SCP or LSC. Outcomes and complications of RASC were reported.
Follow-up	**Mean follow-up not reported**
Conflict of interest/source of funding	None

Analysis

Follow-up issues:

- Studies reviewed by 2 independent researchers
- When data from original papers wasn't clearly interpretable, the corresponding authors were contacted by email.

Study design issues:

- Some studies included in this systematic review present results of women having sacrocolpopexy and a concomitant hysterectomy

Study population issues: About 38% of the cases of Sacrocolpopexy cases had associated hysterectomy, 33% had anti-incontinence procedure. Sacrocolpopexy with hysterectomy is analysed in a separate piece of NICE guidance currently under review (IP 727/2). Subgroup analyses of patients not having hysterectomy were reported when available.

Other issues: One study (Paraiso 2011) included in this systematic review and meta-analysis was also included in the paper by Maher, Study 1 Table 2.

Key efficacy and safety findings

Efficacy

n=**1,488 patients from 27 studies**

Success and patient satisfaction with RASC

Outcome	Incidence	Success rate
Objective cure (apical prolapse)	<1% (2/246)	97% - 100%
Objective cure (all compartments)[a]	6% (66/1029)	84% - 100%
Reoperation	3% (23/687)	
Subjective cure	- [b]	

[a]This considered studies with follow-ups greater than 2 years.

[b]Great heterogeneity in subjective cure reporting.

Prolapse recurrence (all compartments)

RASC versus LSC: OR: 0.75; 95%CI, 0.36-1.57 (n=444), I^2=1%, p=0.40.

Safety

Surgical related complications (n=1488)

RASC associated[a] (3% 48/1488)	
Vaginotomy	1% (14/1488)
Bladder injury	2% (26/1488)
Ureteral injury	<1% (1/1488)
Bowel injury	<1% (4/1488)
Postoperative complications[b] (2% 20/1118)	
Bowel obstruction	<1% (5/1118)
Port site hernia	<1% (6/1118)
Port site nerve entrapment	<1% (1/1118)
Abscess	<1% (3/1118)
Peritonitis due to bowel injury	<1% (2/1118)
Vaginal cuff dehiscence	<1% (1/1118)
Feeling of traction requiring repeated surgery	<1% (2/1118)

[a]Satava grade 2 and 3 complications. There was significant heterogeneity among studies (p<0.001). There was 1 case of suture and needle being lost requiring a 2cm incision for retrieval.

[b]Severe complications, Claven-Dindo grade ≥ 3a, no grade 4 or 5 complications reported.

Intraoperative complications

RASC versus LSC: OR: 1.05; 95%CI, 0.52-2.12 (n=443), I^2=0%, p=0.94.

Conversion

RASC versus LSC: OR: 0.89; 95%CI, 0.25-3.19 (n=443), I^2=0%, p=0.72.

Postoperative complications (all grades)

RASC versus LSC: OR: 1.85; 95%CI, 0.96-3.75 (n=350), I^2=37%, p=0.18.

Severe postoperative complications (grade≥3)

RASC versus LSC: OR: 0.56; 95%CI, 0.36-2.83 (n=430), I^2=24%, p=0.73.

Mesh Erosion

RASC versus LSC: OR: 1.82; 95%CI, 0.51-6.45 (n=438), I^2=0%, p=0.86.

The incidence of mesh erosion ranged from 0% and 8% but there was significant heterogeneity amongst studies (p<0.01).

Possible risk factors include vaginotomy and concomitant total hysterectomy.

One study comparing RASC and total hysterectomy with RASC with supracervical hysterectomy reported that total hysterectomy had an increased risk of mesh erosion (0% following supracervical versus 14% following total hysterectomy, p=0.008, LE 2b).

Lightweight mesh could be considered a protective factor. Comparing patients with specific information available 3 mesh erosions (1%) of 275 patients that had lightweight polypropylene mesh versus 26 mesh erosions (3.6%) among 715 women who had standard weight polypropylene mesh (p=0.03, Odds Ratio:0.3, 95%CI, 0.08-0.97). This is reported as being highly susceptible to bias.

Abbreviations used: CI, confidence interval; LE, level of evidence; LSC, laparoscopic sacrocolpopexy; OR, odds ratio; RASC, robot assisted sacrocolpopexy; SCP, sacrocolpopexy.

Study 4 Nygaard I (2013)

Details

Study type	**RCT**
Country	USA
Recruitment period	2002 to 2005
Study population and number	n= 215 (104 SCP and urethropexy versus 111 SCP only) Adult women seeking treatment for apical pelvic organ prolapse with uterine preservation.
Age and sex	Female, 61.9 (mean)
Patient selection criteria	Women completing the in-person 2 year CARE visit follow-up were recruited into the extended CARE study, 92% (215/233) were included.
Technique	The CARE RCT compared the outcomes of women that had sacrocolpopexy for POP with or without concomitant Burch urethropexy (prophylactic antiincontinence procedure).
Follow-up	**7 years (median)**
Conflict of interest/source of funding	One of the authors reported serving as a consultant to Johnson & Johnson and Key Tech. One other author reported receiving research grantes from Pelvalon, Astellas, University of California/Pfiser, Pfiser, and Xanodyne; and serving as consultant to Astellas (advisory board), GlaxoSmithKline, uromedica, IDEO, Pfiser and xanodyne. Another author reported serving as a consultant to Intuitive surgical.

Analysis

Follow-up issues: 34/215(16%) women were lost to follow-up at year 5, 55/215(26%) at year 7. Follow-up extended up to 9 years but year 8 and 9 were excluded from the analysis because of small numbers.

Study design issues:

Due to lack of funding some of the sites follow-up was stopped, decreasing follow-up rates and limiting the number of participants. The study wasn't powered to detect differences inferior to 15%.

The study surgeries were performed by 21 surgeons from 7 sites.

Study population issues: None

Other issues: none.

Key efficacy and safety findings

Efficacy

n= 215 (104 SCP and urethropexy versus 111 SCP only)

Estimated probability of failure from parametric survival models 2 and 7 years after abdominal sacrocolpopexy.

	2 years follow-up		
	Urethropexy	No urethropexy	Treatment difference (95% CI)
Pelvic organ prolapse			
Symptomatic failure	0.14	0.12	0.026 (-0.032 to 0.087)
Anatomic failure	0.09	0.09	-0.005 (-0.093 to 0.087)
Composite* failure	0.22	0.18	0.035 (-0.101 to 0.164)
Urinary incontinence			
Stress	0.44	0.61	-0.175 (-0.296 to -0.043)
Overall	0.59	0.67	-0.082 (-0.203 to 0.041)

	7 years follow-up		
	Urethropexy	No urethropexy	Treatment difference (95% CI)
Pelvic organ prolapse			
Symptomatic failure	0.29	0.24	0.049 (-0.060 to 0.162)
Anatomic failure	0.27	0.22	0.05 (-0.161 to 0.271)
Composite* failure	0.48	0.34	0.134 (-0.096 to 0.322)
Urinary incontinence			
Stress	0.62	0.77	-0.154 (-0.266 to -0.037)
Overall	0.75	0.81	-0.064 (-0.161 to 0.032)

*anatomic or symptomatic failure

Safety

Frequency of suture and mesh erosion in women enrolled in CARE and extended care

	2 years	7 years
Suture erosion	0.9% (3/322)	1.2% (4/322)
Mesh erosion	5.3% (17/322)	9.9% (32/322)

Erosion occurred with all types of mesh. Overall probability of mesh erosion at 6.18 years was 10.5% (95% CI, 6.8%16.1%) when right censoring time was the last clinic visit.

When the right censoring time was either a clinic visit or a last telephone interview probability of mesh erosion was 9.9% (95%CI, 6.5% to 15%).

Of the 23 women with mesh erosion, 11 were in the urethropexy group and 12 in the control group.

In the CARE and extended CARE sample 15 had excision in the operating room (13 vaginal and 2 abdominal), 4 were given oestrogen cream and 4 were asymptomatic.

7 women in the urethropexy group and 13 in the no urethropexy group had either surgery or received a urethral bulking agent injection.

7 women in the urethropexy group and 5 women in the control group had either surgery or pessary for POP

By year 7 at least 16% (36/215) of women in the extended CARE had additional surgery related to pelvic floor disorders: 11 recurrent POP, 14 for SUI and 11 for mesh complications.

Abbreviations used: CARE, Colpopexy reduction efforts; CI, confidence interval LSC, laparoscopic sacrocolpopexy; POP, pelvic organ prolapse; RCT, randomised control trial; RSC, robotic sacrocolpopexy; SCP, sacrocolpopexy.

Study 5 Tate SB (2010)

Details

Study type	**RCT**
Country	USA
Recruitment period	2001 to 2003
Study population and number	n=**100 (29/54 polypropylene mesh versus 29/46 fascia lata group at follow-up)**
Age and sex	Adult women, mean age 58 ± 9 years
Patient selection criteria	Women enrolled in the double-blinded RCT comparing polypropylene and cadaveric fascia lata for sacrocolpopexy and completing 1 year follow-up were suitable to be included in the 5 years follow-up.
Technique	After selecting sacrocolpopexy as a treatment for POP each patient was randomised to polypropylene mesh and cadaveric fascia lata and followed-up for 1 year. After completion of the 1 year follow-up women would have the opportunity of taking part in the 5 years follow-up.
Follow-up	**5 years**
Conflict of interest/source of funding	One of the authors is a consultant and a paid instructor of CR Bard. Another author is a consultant and a paid instructor of CR Bard, receives research support from Solace Therapeutics, receives research support from and is a consultant and paid instructor at Boston Scientific and is a consultant and a paid instructor for Intuitive Surgical.

Analysis

Follow-up issues:

- Only 58 (58%) of the 100 subjects returned for the 5 year visit, 29/54 from the polypropylene group and 20/46 from the fascia lata group. Eleven individuals (11%) returned only questionnaires and were excluded because didn't have POP-Q examination.
- Lost to follow-up was 31% but wasn't significantly different in either group: Fisher exact test, p=0.42). Rate of follow-up wasn't significantly different between prolapse-stage groups (Fisher's exact test, p=0.53). Individuals whose surgery was an anatomical success were more likely to follow up than year 1 anatomic failures; the differences in the follow-up rates were not significant (Fisher's exact test, p=0.79). These conclusions held for both groups. Year 1 successes were not significantly more likely to follow-up than year 1 failures for the mesh group (p=0.32) or the fascia group (p=1.0). Additionally the difference between successes follow-up at year 1 wasn't significantly different amongst groups (mesh p=0.47, facia p=0.28). Tests were run on a small number of subjects but suggest demographic and clinical similarities on both followed-up and lost to follow-up cohorts, alleviating response bias.

Study design issues:

- A computerised blocked randomisation scheme was held with allocation being submitted in an opaque closed envelope. Only surgeons were not blinded to intervention.
- Data for both studies collected by a single, masked, clinical research nurse.
- After 1 year, the surgeon told the patients which graft material was used. This might have impacted on the description of symptoms.
- No validated instrument was used to collect the information about subjective symptoms of prolapse.

Study population issues: None.

Other issues: None

Key efficacy and safety findings

Efficacy

n=**100 (29/54 polypropylene mesh versus 20/46 fascia lata group)**

Mean ± SD POP-Q measurements and mean POP-Q stage at year 1 to 5, within comparators and between comparators.

	Fascia			**Mesh**			Fascia vs Mesh
	1 year (n=46)	5 years (n=29)	P value[a]	1 year (n=54)	5 years (n=29)	P value[a]	P value[b]
Aa	-1.9±1.2	-1.8±1.5	0.87	-2.5±0.8	-2.6±0.7	0.40	0.66
Ba	-1.9±1.2	-1.8±1.5	0.95	-2.5±0.8	2.6±0.7	0.19	0.46
C	-8.1±2.7	-7.8±1.4	**0.01***	-9±1.2	-8.1±1.4	**0.0006***	0.22
Gh	2.4±0.7	2.5±0.7	0.51	2.3±0.6	2.4±0.8	0.95	0.42
Pb	3.4±0.7	3.2±0.8	**0.02**	3.6±0.8	3.1±1	0.31	0.36
TVL	9.3±1	8.4±1.2	**0.0007***	9.4±1	8.5±1.1	**0.0006***	0.46
Ap	-2.7±0.6	-2.7±0.8	1.00	-2.9±0.3	-2.9±0.3	1.0	0.79
Bp	-2.7±0.6	2.7±0.8	1.00	-2.9±0.3	-2.9±0.3	1.0	0.79
Stage	1±0.9	1±1	0.88	0.6±0.7	0.5±0.6	0.61	0.66

[a] Signed rank test for within treatment group comparisons

[b] Rank sum test for the treatment group comparisons

*despite statistically significant these differences weren't clinically significant

Success rates at 1 and 5 years follow-up

Definition	1 year polypropylene mesh (6)	1 year Cadaveric fascia (6)	P value	5 year poplypropylene mesh	5 year Cadaveric fascia	P
Objective anatomic	41/45 (91%)	30/44 (68%)	0.007[a]	27/29 (93%)	18/29 (62%)	0.02[b]
Clinical	NA	NA	-	28/29 (97%)	26/29 (90%)	0.61[b]

[a] P value is from Chi-squared test

[b] P values are from Fisher's exact test

Objective anatomic and clinical failure frequencies

	Fascia lata (n=29)	**Mesh (n=29)**
Subjective complaints	-	-
Vaginal bulge	13% (4/29)	-
Symptoms of prolapse	10% (3/29)	-
Any POP-Q point>0	10% (3/29)	-
POP-Q point C1/2 TVL	-	--
Surgical re-treatment	3%(1/29)	3% (1/29)
Failure by clinical definition [a]	10% (3/29)	-
Failure by objective anatomic definition [b]	38% (11/29)	7% (2/29)

[a]Complaints of vaginal bulge or symptoms of prolapse and a POP-Q point>0 or POP-Q pointC>1/2 TVL

[b]POP-Q point≥-1 (≥stage 2)

Safety

Year 1 follow-up

There were 2 graft erosions, 1 in each treatment group. The polypropylene mesh erosion occurred at the posterior wall and eroded to the rectum requiring bowel resection and formation of colostomy. The subject was lost to follow-up.

The subject with fascia lata graft erosion was lost to follow-up between years 1 and 5. At the year 5 visit the fascial erosion persisted and the patient presented with post-coital spotting, dyspareunia, vaginal discharge and odour.

Year 5 follow up

There was 1 additional erosion in the polypropylene mesh group. The subject had a 2x3 cm apical mesh erosion. Laparoscopic vaginal removal of the mesh was needed. Necrotising fasciitis was developed post-operatively at the umbilical port site. The patient had a long stay in hospitalbut fully recovered.

There were 2 retreated subjects with documented cystocele repairs between original surgery and 5 year follow-up, one in each group.

Abbreviations used: Aa, anterior vaginal wall; Ba, most distal position of the remaining upper anterior vaginal wall; C, most distal edge of cervix or vaginal cuff scar; Gh, genital hiatus; Pb, peritoneal body; TVL, total vaginal length; Ap, posterior vaginal wall 3 cm proximal to the hymen, Bp, most distal portion of the remaining upper posterior vaginal wall

BPCI, confidence interval; NA, not applicable; POP, pelvic organ prolapse; POP-Q, Pelvic organ prolapse quantification system; RCT, Randomised control study.

Study 6 Sarlos D (2013)

Details

Study type	**Prospective case series**
Country	Switzerland
Recruitment period	Initial prospective case series recruited between 2003 and 2007 Long term follow-up exam occurred between July and September 2011
Study population and number	n= **101**, adult women
Age and sex	Age not reported.
Patient selection criteria	101 cases of LSC for uterine and post-hysterectomy prolapse enrolled in a prospective cohort with 12 months follow-up. Five years after surgery 99 of the 101 women were invited to a follow-up.
Technique	Women that decided to complete the 5 years follow-up had clinical examination and were asked to fill out two questionnaires: the German version of the Kings Health Questionnaire and a validated German version of the POP questionnaire. The degree of prolapse was documented using the POP-Q classification
Follow-up	**60 months (mean)**
Conflict of interest/source of funding	None.

Analysis

Follow-up issues:

- Only 85 of the 101 (84%) women included in the initial cohort participated in the long term follow-up. From these, 17 patients could not come to the outpatient clinic because of age and comorbidities or relocation. Full follow-up was obtained for 68 women. There were 14 patients lost to follow-up.

Study design issues:

- Data from the 68 patients completing full follow-up was used to calculate the objective cure rates. For the subjective cure rates data from all 85 women was used.
- Surgical procedures were performed by 2 senior urogynaecologists experienced in LSC.

Study population issues: None.

Other issues: None

Key efficacy and safety findings

Efficacy

Objective and subjective cure rates after LSC

	12 months (n=99)		60 months (n=68)	
	Total number	**%**	**Total number**	**%**
Subjective cure rate[a]	97/99	98.0	81/85 (81/99)	95 (82)
Objective cure rate	91/99	92	57/68 (57/99)	84 (58)
Recurrence of anterior wall	6/99	6	6/68(37)	9 (37)
Recurrence of posterior wall	2/99	2	4/68 (35)	6 (35)
Apical recurrence	0	0	1/68 (32)	1 (32)
QoL score[d]	9.1	-	8.3	-

Objective cure after LSC[b]

POP-Q	Pre-operatively (n=99)	12 months (n=99)	60 months (n=68)
Aa	-1 (±1.8)	-2 (±0.4)	- 2 (±1.0)
Ba	1(±2.3)	-2 (±1.5)	-2 (±1.5)
C	-1 (±3.4)	-7 (±2)	-6 (±1.2)
Ap	-2 (±1.3)	-3 (±0.6)	-3 (±0.6)
Bp	-2 (±3.1)	-3 (±1.1)	-3 (±3.2)

Safety

Safety events after LSC

	12 months (n=99)		60 months (n=85)	
	Total number	**%**	**Total number**	**%**
De novo SUI	24	24	32	38
Surgery for post-operative SUI	15	15	16	19
Post-operative constipation	1	1	4	5
Post-operative voiding disorders	8	8	11	13
De novo urge incontinence	2	2	7	8
Severe de novo dyspareunia	1/47	2[c]	10/41	24
Mesh erosion	1	1	2	3

There were 2 post-operative mesh protrusions into the bladder, 1 case happened 12 months after surgery and another case 60 months. Both cases had incidental bladder incision during LSC. Protruded mesh was removed by laparoscopy with partial excision of the anterior mesh and reconstruction of the bladder.

Abbreviations used: Aa, anterior vaginal wall; Ap, posterior vaginal wall 3 cm proximal to the hymen; Ba, most distal position of the remaining upper anterior vaginal wall; Bp, most distal portion of the remaining upper posterior vaginal wall; C, most distal edge of cervix or vaginal cuff scar; LSC, laparoscopic sacrocolpopexy; POP, pelvic organ prolapse; QoL, quality of life; POP-Q, pelvic organ prolapse quantification system; SUI, Stress urinary incontinence.

[a]In parentheses: number and percentage if every dropout is counted as a failure

[b]Results are given as mean and standard deviation in parenthesis

[c]As only 41 (60 months follow-up) and 47 (at 12 months follow-up) declared themselves as sexually active, 41 or 47 were taken as 100%)

[d]Quality of life assessed using a visual analogue scale from 1 to 10. Pre-operatively the quality of life index was 5.6

Study 7 Linder BJ (2015)

Details

Study type	**Prospective case series**
Country	USA
Recruitment period	2002 and 2012
Study population and number	**n=70,** adult women
Age and sex	67 years (Median) , IQR [59-74]
Patient selection criteria	84 consecutive patients having RASC at the Mayo Clinic (Rochester, USA). Patients were excluded if RASC was converted to SCP.
Technique	ASC was selected after counselling regarding best treatment options. Patients were given 10-point Likert scale as well as PFDI and PFIQ-7 questionnaires to answer.
Follow-up	**72 months (Median)** [IQR 39-144]
Conflict of interest/source of funding	None.

Analysis
Follow-up issues:

Study design issues:
- All women were treated by a fellowship-trained female pelvic reconstructive surgeon and a fellowship-trained minimally-invasive urologist.
- Some of the patients had a concomitant anti-incontinence procedure at the time of RASC (robot assisted sacrocolpopexy).
- Some patients were excluded as they had RASC converted to SCP (n=14). This was because of inability to dissect secondary to scarring, dense abdominal adhesions and failure to progress during pre-sacral dissection.

Study population issues: Concomitant midurethral sling was carried out in 55 (79%) patients

Other issues: None

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>

n=70, adult women

<table>
<tr><td colspan="2">Objective failure rate (n=70)</td></tr>
<tr><td>Repeated surgery[a]</td><td>1 years = 2%
3 years = 5%
6 years= 10%
(frequencies not reported)</td></tr>
<tr><td colspan="2">Subjective failure rate (n=40)[b]</td></tr>
<tr><td>Would recommend procedure to relative or friend</td><td>55% (22/40)</td></tr>
<tr><td>Would probably recommend procedure to relative or friend</td><td>25% (10/40)</td></tr>
<tr><td>Overall satisfaction[c]</td><td>10 [IQR 8-10]</td></tr>
<tr><td>Symptomatic improvement[d]</td><td>9 [IQR 8-10]</td></tr>
</table>

[a]repeated surgeries included 2 patients having anterior colporrhaphy and 1 patient treated by posterior colporrhaphy. There was 1 case of apical prolapse at 128 months (10 years) follow-up.

[b]Median follow-up was 90 months [IQR 56-120 months].

[c]Median response to the question “How successful has your treatment for prolapse been?”, on a Likert scale (0=not at all success, 10=very successful).

[d]Median post-operative symptomatic improvement, evaluated on a Likert scale, (0=much worse, 10=much better).

Further symptomatic follow-up*

<table>
<tr><th>Scale</th><th>Score</th><th>Median [IQR]</th></tr>
<tr><td>PFDI-20</td><td></td><td></td></tr>
<tr><td>POP Distress inventory-6</td><td>25-100</td><td>29.2 (25-37.5)</td></tr>
<tr><td>Colorectal-anal Distress Inventory-8</td><td>25-100</td><td>40.6 (28.1-47.7)</td></tr>
<tr><td>Urinary Distress Inventory-6</td><td>25-100</td><td>45 (35-60)</td></tr>
<tr><td>PFIQ-7</td><td></td><td></td></tr>
<tr><td>Total Score</td><td>0-300</td><td>0 (0-28.6)</td></tr>
<tr><td>Bladder</td><td>0-100</td><td>0 (0-19)</td></tr>
<tr><td>Bowel</td><td>0-100</td><td>0 (0-4.8)</td></tr>
<tr><td>Pelvis</td><td>0-100</td><td>0 (0-4.8)</td></tr>
</table>

*Median follow-up for patients that did not complete a questionnaire at last follow-up was 49 months [IQR 8-93]

</td><td>

8.6% (6/70) had a total of 6 surgeries for recurrent prolapse or mesh complication.

2.7% (2/70) vaginal extrusion

</td></tr>
<tr><td colspan="2">Abbreviations used: IQR, Interquartile range; LSC, laparoscopic sacrocolpopexy; PFDI-20, pelvic floor distress inventory questionnaire; PFIQ-7, ; POP, pelvic organ prolapse; RASC, robot assisted sacrocolpopexy; SCP, sacrocolpopexy;</td></tr>
</table>

Study 8 Granese R (2009)

Details

Study type	Prospective case series
Country	Italy
Recruitment period	1999 to 2007
Study population and number	n=**165**
Age and sex	Mean 67 years (range 58-76 years, SD 19.22)
Patient selection criteria	Women with diagnosis of vaginal vault prolapse between 2nd and 4th degree, according to HWS classification, that had LSC.
Technique	All women had a urogynaecological work-up before surgery, including a physical vulvovaginal examination* and an instrumental evaluation** with urodynamic investigation. During LSC mesh was always inserted laparoscopically.
Follow-up	**Median 43 months (range 6-96 months)**
Conflict of interest/source of funding	Not reported.

*****Evaluation of descensus, urethra mobility test: Q-tip, perineal muscular balance, stress test/urinary incontinence test, proctologic evaluation, rectovaginal exploration in othostatism, post-urination residual evaluation.
**Cystometry, uroflowmetry, valsalva leak point pressures, urethra pressure profile.

Analysis

Follow-up issues:
- At 1, 6, 12 months after surgery, a physical examination was carried out for all patients. After this period, women were contacted annually. Patients not able to be present in some of the follow-ups were contacted by phone and asked about the presence or absence of prolapse, urinary and bowel symptoms.
- There were 27 patients that were lost to follow-up: 4 died since surgery, 18 could not be contacted anymore and 5 declined to participate at follow-up.

Study design issues:
- None.

Study population issues:
Among the 165 women, 33 had already had other surgical procedures: 15 posterior colporraphy without relapse and 18 anterior colporraphy with 2 presenting a 2nd degree cystocoele at the moment of LSC, and were therefore treated again. All additional corrections, except the enterocele and rectocele repairs were carried out after LSC. When necessary, a perineorraphy was also performed at the end of surgery.

Other issues: None

Key efficacy and safety findings

Efficacy

n=165

Objective cure rates (Median 43 months)

Successful treatment was achieved in 95% (131/138) patients.

Summary of symptoms before LSC and at follow-up

	Before treatment	43 months (median)[a]
Vaginal vault prolapse symptoms		
Vaginal lump	83% (115/138)[b]	7% (10/138)
Lower abdominal pain	69% (95/138)[c]	4% (6/138)
Urinary symptoms		
Nycturia	17% (24/138)	4% (4/138)
Dysuria	9% (13/138)	3% (4/138)
Stress incontinence	4% (5/138)	7% (11/138)
Mixed incontinence	17% (23/138)	14% (20/138)
Pollakiuria	13% (18/138)	7% (10/138)
Voiding dysfunctions	16% (22/138)	7% (9/138)
Urge incontinence	11% (15/138)	18% (25/138)
Recurrent urinary tract infections	16% (22/138)	5% (7/138)
Bowel symptoms		
Constipation	7% (10/138)	13% (18/138)
Obstructed defecation	1% (2/138)	6% (8/138)
Urgency	0	2% (3/128)
Pelvic pressure	67% (92/138)	9% (12/138)
False urge to defecate	51% (70/138)	5% (7/138)

Patient satisfaction

	Rate
Quite satisfied	83% (115/138)
Satisfied enough	12%(16/138)
Not satisfied	5% (7/138)

Safety

Symptoms after 8 years follow-up

De novo urinary incontinence was present in 5% (7/138) of patients.

Type of prolapse	Recurrence of prolapse	New prolapse
Vault prolapse	5% (7/138)*	-
Rectocele	1% (1/138)	12% (16/138)
Cystocele	4% (5/138)	8% (11/138)
Enterocele	-	1% (2/138)

*Recurrent vaginal prolapse was registered in 7 patients, in 3 the vaginal vault detached after a period of 7-20 days and was caused by the use of Vyprol (hence use of same has been suspended). In another 3 women (2 affected by 3rd degree prolapse and 1 by 2nd degree prolapse) the mesh detached after less than 1 month. These cases were performed by a less experienced surgeon and prolapse was associated with inefficient suturing. There was only 1 case of mesh erosion and vaginal protrusion. The mesh was removed.

Postoperative complications included 10 cases of fever, 5 cases of lumbosciatica , 15 cases of detrusor overactivity, 2 cases of vaginal haematoma and 5 cases of minimal dyspareunia (2 cases persisted and 3 cases resolved spontaneously).

Abbreviations used: HWS, half way system classification by Baden and Walker; LSC, laparoscopic sacrocolpopexy; SD, standard deviation.

[a]Median follow-up 43 months (range 6-96)

[b]In all patients except 25 women affected by 2nd degree virginal vault prolapse.

[c]In all patients affected by 4th degree vault prolapse and all patients affected by 3rd degree prolapse except 9.

Efficacy

Subjective failure rate

In a systematic review and meta-analysis of 5,954 women from 56 randomised control trials (RCTs) comparing surgery for pelvic organ prolapse, 10 studies compared surgery for apical vaginal prolapse repair. In 3 RCTs comparing abdominal sacrocolpopexy (SCP) with vaginal sacrospinous colpopexy (VSC), there was no statistically significant difference in the rate of subjective failure (11% [9/84] versus 21% [18/85], relative risk (RR) 0.53; 95% confidence interval [CI] 0.25 to 1.09).[1]

In an RCT of 215 patients comparing 111 women that had SCP alone with 104 women treated by SCP combined with urethropexy, symptomatic failure was greater (but not statistically significant) in the urethropexy group than in the SCP alone group at 2-year follow-up, treatment difference 0.026, 95% CI -0.032 to 0.087. This remained true at 7-year follow-up with a treatment difference of 0.049, 95%CI -0.060 to 0.162.[4]

In an RCT of 100 patients that compared SCP with polypropylene mesh (n=54) to SCP with cadaveric fascia lata (n=46), there were no subjective complaints in the mesh group compared with 13% (4/29) of patients reporting vaginal bulge and 10% (3/29) of patients reporting symptoms of prolapse in the fascia lata group, within 5-year follow-up, p value not reported.[5]

In a prospective case series of 101 women treated by laparoscopic sacrocolpopexy (LSC), subjective cure rates were 98% (97/99) at the end of 12 months and 95% (81/85) at the end of 60 months, p value not reported. [6]

Objective failure rate

In the systematic review and meta-analysis of 5,954 women from 56 RCTs, there were statistically significantly fewer women who did not improve to stage 2 (that is, the leading edge of the vagina descending within 1 cm of the hymen) or better in the SCP group than in the VSC group in 1 single centre RCT (6% [3/52] versus 20% [13/66], RR 0.29; 95% CI 0.09 to 0.97, median follow-up of 2 years). In another RCT with 2-year follow-up, included in the same systematic review, laparoscopic sacrocolpopexy (LSC) was statistically significantly better than total vaginal propylene mesh repair in reducing prolapse to less than stage 2 (23% [12/53] versus 58% [32/55], RR 0.39; 95% CI 0.23 to 0.67).[1]

In a systematic review of 1,176 women (from 13 comparative studies), mesh SCP was compared with native tissue repair. Prolapse reduction success was defined as a less than stage 2 prolapse or an above the hymen measurement. For a follow-up period between 1 and 2.5 years the meta-analysis of 4 RCTs from this systematic review reported that mesh SCP had statistically significantly

better objective cure rates than native tissue vaginal repair (75% [132/177] versus 62% [119/192], odds ratio (OR) 2.04; 95% CI 1.12 to 3.72, I2=31%). One comparative study included in this paper reports a statistically significantly higher recurrence of posterior wall prolapse after LSC (17% [10/60]) than after sacrospinous ligament fixation (0/51, p<0.01).[2]

The systematic review of 5,954 women reported that SCP had a statistically significantly lower rate of recurrent vaginal vault prolapse (4% [3/84]) than VSC (15% [13/85]) in a meta-analysis of 2 RCTs (RR 0.23; 95%CI, 0.07-0.77 I2=0%, p=0.018). No statistically significant differences were found between SCP and VSC for any pelvic organ prolapse 24 % (11/46) versus 31% (13/42), respectively: RR 0.77; 95%CI, 0.39-1.53.[1]

The systematic review of 5,954 women included 1 RCT that reported a statistically significantly lower objective recurrence rate for LSC compared with TVM (23% [12/53] versus 100% [32/55]; RR 0.39; 95%CI 0.23-0.67) at a 2-year follow-up. [1]

In a systematic review and meta-analysis of 1,488 patients from 27 studies (17 single arm and 10 comparative studies) the objective failure rate (apical prolapse) was less than 1% (2/246). For all compartments prolapse the failure rate was 6% (66/1,029), for a minimum 2-year follow-up. [3]

In the RCT of 215 women comparing 111 women treated by SCP alone with 104 women treated by SCP with urethropexy, there was no statistically significant difference in anatomic failure at 2-year follow-up (treatment difference: -0.005, 95%CI -0.093 to 0.087) or at the end of the 7-year follow-up (treatment difference: 0.05, 95%CI -0.161 to 0.271).[4]

In the RCT of 100 patients comparing SCP using polypropylene mesh with SCP using cadaveric fascia lata overall objective anatomic success was statistically significantly higher in the polypropylene group (93% [27/29]) than in the fascia lata group (62% (18/29) at 5-year follow-up, p=0.02.[5]

A case series of 165 women treated by LSC reported recurrence of vault prolapse in 5% (7/138) of women, recurrent rectocele in 1% (1/138) and cystocele in 4% (5/138) of women at the end of 8-year follow-up.[8]

In the prospective case series of 101 women treated by LSC, objective cure rate was 92% (91/99) at month 12 and 84% (57/68) after 60 months. Recurrence of anterior wall prolapse was 6% (6/99) and 9% (6/68) at 12 and 60 months,

respectively. Recurrence of posterior wall prolapse was 2% (2/99) and 6% (4/68) at 12 and 60 months respectively.[6]

In the prospective case series of 165 women treated by LSC, objective cure rates was 95% (131/138) within a median follow-up of 43 months .[8]

POP-Q measurements

Objective success was reported by some studies through specific point measurements, using the pelvic organ prolapse quantification system (POP-Q).

One single RCT included in the systematic review and meta-analysis of 5,954 women, comparing elevation of the vaginal vault above the hymen (point C) at 1-year follow-up found no statistically significant difference between SCP (6.6cm) and LSC (6.7cm): mean difference (MD): 0.0, p=0.71, 95%CI: -0.74 to 0.74. One RCT with 2-year follow-up from the same systematic review revealed point C was statistically significantly higher following LSC compared with TVM, MD: 1.39cm 95%CI: 0.39 to 2.39. Point C was also higher when colposuspension and SCP were compared with SCP alone with statistically significantly better results for the combined group: RR: 0.41, 95% CI: 0.13-0.69, I^2=46%, p=0.0046. Point Ba (middle anterior vaginal wall), Bp (mid-point posterior vaginal wall) and total vaginal length (TVL) were also statistically significantly higher after LSC in comparison to TVM (n=108) at 2-year review: Ba MD= 0.70, 95%CI: 0.36 to 1.04, p≤0.0001; Bp MD: 0.70, 95%CI: 0.37 to 1.03, p≤0.0001 and TVL MD: 1.0, 95%CI: 0.6-1.4.[1]

In the RCT of 100 patients comparing SCP with polypropylene mesh (29/54) to SCP with cadaveric fascia lata (20/46) there was no statistically significant difference for any of the POP-Q measurements at the end of 5-year follow-up.[5]

Patient satisfaction

In the systematic review and meta-analysis of 5,954 women from 56 RCTs 1 RCT (Maher 2011) reported 2% (1/53) of patients in the SCP group were unsatisfied compared with 7% (4/55) of patients treated by VSC. The difference was not statistically significant, RR 0.82; 95%CI 0.32 to2.06 (n=89).[1]

In a prospective case series of 70 women treated by robot-assisted sacrocolpopexy (RASC), 55% (22/40) would recommend the procedure to a relative or friend, 25% (10/40) would probably recommend procedure and overall satisfaction was 10 (0=not at all success, 10=very successful) at the median follow-up time of 90 months. The average symptomatic improvement was 9 (0=much worse, 10=much better). The median scores for the pelvic floor distress inventory (PFDI-20) (score 25-100) were: POP distress inventory 29.2 (IQR 25-37.5), colorectal-anal distress Inventory-8 40.6 (IQR 28.1-47.7) and Urinary

Distress Inventory-6 45 (IQR 35-60). The median total score for the pelvic floor impact questionnaire short form 7 (PFIQ-7) (score 0-300) was 0 (0-28.6).[7]

In the prospective case series of 165 women treated by LSC, 83% (115/138) of women were “quite satisfied”, 12% (16/138) were “satisfied enough” and 5% (7/138) were “not satisfied”.[8]

Improvement of urinary symptoms

In the systematic review and meta-analysis of 5,954 women from 56 RCTs, 2 RCTs (n=128) showed there was a statistically significant lower rate of stress incontinence (SUI) in women treated by SCP (30% [14/47]) than in women treated by VSC (35% [28/81]: RR 0.55; 95%CI 0.32 to0.95).[1]

In the RCT of 215 women the rate of SUI was statistically significantly higher in the SCP only group when compared with the SCP with urethropexy, treatment difference: -0.175; 95% CI -0.296 to -0.043, at 2-year follow-up. Treatment difference loses statistical significance in overall urinary incontinence: -0.082; 95%CI -0.203 to 0.041. The trend remains at the end of 7-year follow-up with rates of SUI being statistically significantly lower in the urethropexy group, treatment difference: -0.154; 95%CI -0.266 to -0.037. The treatment difference for overall causes of urinary incontinence was not statistically significant, treatment difference: -0.064; 95% CI -0.161 to 0.032.[4]

In the prospective case series of 165 women a number of urinary symptoms improved at the end of the 43-month follow-up: nycturia complaints reduced from 17% (24/138) to 4% (4/138), dysuria reduced from 9% (13/138) to 3% (4/138), mixed incontinence decreased from 17% (23/138) to 14% (20/138), pollakiuria reduced from 13% (18/138) to 7% (10/138), voiding dysfunctions decreased from 16% (22/138) to 7% (9/138) and recurrent urinary tract infections incidence also decreased from 16% (22/138) to 5% (7/138). Some symptoms had worsened at the end of the 43 months. These included stress incontinence that was reported by 4% (5/138) of the women and increased to 7% (11/138), urge incontinence that increased from 11% (15/138) to 18% (25/138).[8]

Improvement of bowel symptoms

The prospective case series of 165 women reported that constipation rates increased from 7% (10/138) before surgery to 13% (18/138) at the end of follow-up, and obstructed defecation increased from 1% (2/138) to 6% (8/138). Urgency was not reported by any women before surgery and it was reported in 2% (3/138) of women at the end of 43 months. The incidence of pelvic pressure symptoms reduced from 67% (92/138) to 9% (12/138) at the end of follow-up. Similarly, the

incidence of false urge to defecate reduced from 51% (70/138) of women at baseline to 5% (7/138) at 43 months.[8]

Improvement in dyspareunia

In the systematic review and meta-analysis of 5,954 women from 56 RCTs, 3 RCTs reported that reduction in post-operative dyspareunia was greater in the SCP group than in the VSC group (15% [7/45] compared to 36% [22/61], RR: 0.39; 95%CI 0.18 to0.86).[1]

Improvement of disease-specific quality of life

In the prospective case series of 101 women treated by LSC, the quality-of-life score improved from 5.6 at baseline to 9.1 at 12 months and 8.3 at 60 months (measured on a visual analogue scale between 1 and 10).[6]

Improvement in symptoms

In the prospective case series of 165 women vaginal lump was reported by 83% (115/138) of women before treatment and by 7% (10/138) at 43-month follow-up. Similarly, lower abdominal pain was present in 69% (95/138) of the women before the procedure and in 4% (6/138) at 43 months.[8]

Safety

Death and admission to ICU

Incidence of death was not statistically significantly different in women treated by abdominal sacrocolpopexy (SCP) using mesh (0/503) compared with women treated by native tissue (less than 1% [1/582]; odds ratio [OR]: 0.14; 95% confidence interval [CI] 0.003 to 6.97) in the analysis of comparative studies reported in the systematic review and meta-analysis of 1,176 women. Postoperative admission to intensive care was not significantly different in the SCP using mesh group (1% [3/561]) compared with the native tissue repair group (0/506; OR 4.64; 95% CI 0.42 to 50.6) in the analysis of comparative studies in the same systematic review.[2]

Incidence of death was not statistically significantly different in women treated by SCP using mesh <1% (6/3343) compared with women treated by native tissue <1% (12/4105) (p=0.61) in the analysis of non-comparative studies reported in the systematic review and meta-analysis of 1,176 women. Postoperative admission to intensive care was not statistically significantly different in the SCP using mesh group (6% [281/4233]) compared to the native tissue repair group (1% [27/3532], p=0.11) in the analysis of non-comparative studies in the same systematic review.[2]

Deep Vein Thrombosis and Pulmonary embolism

Deep vein thrombosis or pulmonary embolism was not statistically significantly different between the SCP using mesh (less than 1% [2/569]) and the native tissue repair group (less than 1% [1/599],OR 1.36; 95% CI 0.14 to13.7) in women included in comparative studies from the same analysis. Deep vein thrombosis or pulmonary embolism was statistically significantly higher in the SCP using mesh (1% [46/4,579] than in the native tissue repair group (less than1% [8/4,114],p=0.03) in women included in non-comparative studies from the same analysis.[2]

Mesh erosion

Mesh exposure risk was not statistically significantly different in women treated by LSC (1/53) in comparison to TVM 13% (7/55) RR: 0.15, 95%CI, 0.02-1.16 at 2-year follow-up in 2 RCTs reported in the systematic review and meta-analysis of 5,954. Mesh exposure risk was statistically significantly smaller in patients treated by SCP using permanent polypropylene mesh 9% (4/45) compared with SCP using cadaveric fascia lata graft 32% (14/44) (RR: 3.58 95%CI: 1.28-10.03, in a trial reported in the same systematic review.[1]

Mesh or suture complications were statistically significantly more frequent in patients treated by SCP using mesh (4% [28/650]) compared with patients who had native tissue repairs (1% [6/537], OR 3.26; 95% CI1.62 to 6.56) in an analysis of comparative studies in the systematic review of 1,176 women. Mesh or suture complications were statistically significantly more frequent in patients treated by SCP using mesh (4% [348/7,831]) than in patients treated by native tissue repair (less than 1% [13/1169], p<0.001) in the analysis of 40 SCP versus 11 native tissue repair non-comparative studies.[2]

Mesh erosion rates were not statistically significantly different when comparing patients treated by robot-assisted sacrocolpopexy (RASC) with patients treated by laparoscopic sacrocolpopexy (LSC,OR 1.82; 95%CI 0.51 to 6.45 [n=438], I^2=0%, p=0.86) in the systematic review of 1,488 patients. The risk of mesh erosion was statistically significantly different in patients treated by RASC with supracervical hysterectomy (0%) compared with patients treated by RASC after total hysterectomy (14%, p=0.008) in 1 comparative study included in the same systematic review.[3]

Mesh erosion rate occurred with all types of mesh with overall probability of 11% (95% CI 7% to 16%) at 6-year follow-up when right censoring was the last clinic visits in the RCT (n=215) comparing 104 patients that had SCP combined with

urethropexy to 111 women that had SCP alone. Mesh erosion rate was 10% (95%CI 7% to 15%) when the right censoring time was either a clinic visit or a last telephone interview.[4]

Graft erosion occurred with the same frequency (1 case in each group) in the group of women treated by SCP with polypropylene mesh compared with SCP with cadaveric fascia lata at 5-year follow-up in the RCT of 100 patients. The polypropylene mesh erosion occurred at the posterior wall and eroded to the rectum needing bowel resection and formation of colostomy. The subject was lost to follow-up. The subject with fascia lata graft erosion was lost to follow-up between year 1 and 5. At the year 5 visit the fascial erosion persisted and the patient presented with post-coital spotting, dyspareunia, vaginal discharge and odour. At 5-year follow-up there was 1 case of additional erosion in the polypropylene mesh group. The subject had a 2x3 cm apical mesh erosion. Laparoscopic vaginal removal of the mesh was needed. Necrotising fasciitis was developed post-operatively at the umbilical port site. The patient had a long stay in hospital but fully recovered.[5]

Mesh erosion rate was 1% (1/99) at 12 months and 3% (2/85) at 60 months in women treated by LSC in the prospective case series of 101 participants.[6]

Reoperation rate

Reoperation rates was similar for women treated by SCP or sacrospinous ligament fixation (SSLF, 13% [6/46] versus 16% [7/43], p=0.67) in an RCT (reported in the systematic review of 1,176 women) with follow-up of 6 to 66 months. Pooled reoperation rates were 7% (46/615) for SCP and 10% (51/511) for native tissue repair (OR 0.76, 95% CI 0.28 to1.09) in 7 comparative studies from the same systematic review and meta-analysis. Pooled reoperation rates in non-comparative studies were 5% (367/7,218) for SCP and 3% (114/3,872) for native tissue repair, (p=0.28) in the systematic review of 1,176 patients.[2]

The reoperation rate was 3% (23/687) in patients treated by RASC reported in the systematic review and meta-analysis of 1,488 patients from 27 studies. Feeling of traction needing reoperation was reported in less than 1% (2/1118) of the patients treated by RASC reported in the same systematic review.[3] Additional surgery was needed in 16% (36/215) of the women included in the RCT (n=215) of 104 patients treated by SCP combined with urethropexy in comparison to 111 women treated by SCP alone, at 7-year follow-up. Causes for reoperation were 11 recurrent POP, 14 for stress urinary incontinence (SUI) and 11 mesh complications.[4]

Reoperation rate was similar in women treated by SCP with polypropylene mesh 3% (1/29) compared with SCP with cadaveric fascia lata 3% (1/29) in the RCT of 100 patients.[5]

Reoperation for SUI in women treated by LSC was reported in 15% (15/99) and 19% (16/85) of patients at 12 and 60 months respectively in the prospective case series of 101.[6]

Reoperation rates in women treated by RASC were 2%, 5% and 10% at years 1, 3 and 6 respectively in the prospective case series of 70 patients.[7]

Incidence of damage to surrounding structures

Nerve injury incidence was not statistically significantly different in patients treated by SCP using mesh 1% (4/514) compared with native tissue repair 1% (7/743) (OR: 0.61[0.18-2.05]) in 5 comparative studies included in the systematic review and meta-analysis of 1,176 women. The incidence of nerve injury was not statistically significantly different in women treated by SCP 4% (96/2,601) compared with native tissue repair 5% (147/2,813) in the analysis of non-comparative studies included in the same systematic review.[2]

The vaginotomy rate in patients treated by RASC was 1% (14/1,488) in the systematic review and meta-analysis of 1,488 patients from 27 studies. Port site nerve entrapment happened in 1% (1/1,118) of the patients in the same systematic review.[3]

Injury to bladder or urethra

Urinary tract injury rate was not statistically significantly different in patients treated by SCP using mesh 2% (20/1068) compared to women treated by native tissue repair 1% (9/1108) (OR: 1.68 [0.79-3.55]) in 8 comparative studies from the systematic review and meta-analysis of 1,176 women. Incidence of urinary tract injury was statistically significantly higher in women treated by SCP using mesh 2% (113/6894) compared to native tissue repair 1% (46/5111) ($p<0.05$) in the analysis of non-comparative studies from the same systematic review and meta-analysis.[2]

Bladder injury rate in patients treated by RASC was 2% (26/1,488) in the systematic review and meta-analysis of 1,488 patients from 27 studies. Ureteral injury incidence was less than1% (1/1,488) in patients from the same systematic review.[3]

Incidental bladder incision happened in 2 patients treated by LSC in the prospective case series of 101 women. Mesh protrusion happened in the same patient: protruded mesh was removed by laparoscopy with partial excision of the anterior mesh and reconstruction of the bladder.[6]

Bowel perforation

Bowel injury rate in women treated by SCP using mesh was not statistically significantly different (1% [8/1,219]) in comparison to native tissue repair patients (1% [10/1,574]) (OR 0.91; 95%CI 0.35 to 2.37) in the analysis comparative

studies from the systematic review and meta-analysis of 1,176 patients. Bowel injury rate was not statistically significantly different in women treated by SCP using mesh 1% (37/6,642) in comparison to women treated by native tissue repair 1% (47/5,744) (p=0.33), in the analysis of non-comparative studies from the same systematic review.[2]

Bowel injury incidence in women treated by RASC was <1% (4/1,488) in the systematic review and meta-analysis of 1,488 patients from 27 studies.[3]

De novo urinary incontinence

De novo SUI rate in women treated by LSC was 24% (24/99) and 38% (32/85) at 12 and 60 months respectively in the prospective case series of 101 women. Post-operative voiding disorders occurred in 8% (8/99) and 13% (11/85) of women at 12 and 60 months respectively in the same patient group. De novo urge incontinence occurred in 2% (2/99) women at 12 months and in 8% (7/85) at 60 months.[6]

Detrusor overactivity rate was 9% (15/165) in the case series of 165 women.[8]

De novo dyspareunia

Dyspareunia rate was statistically significantly lower in women treated by SCP using mesh (5% [23/445]) compared to women treated by native tissue repair 912% [46/384], OR 0.42; 95% CI 0.25 to 0.72) from the analysis of 5 comparative studies reported in the systematic review and meta-analysis of 1,176 women. The rate of dyspareunia was similar for SCP using mesh (12% [371/2,986]) and native tissue repair (9% [200/2,180]; p=0.48) in the analysis of non-comparative studies in the same systematic review.[2]

De novo dyspareunia rate in women treated by LSC was 2% (1/47) and 24% (10/41) at 12 and 60 months respectively in the prospective case series of 101 women.[6]

Minimal dyspareunia incidence in women treated by LSC was 3% (5/165) in the case series of 165 women. It was reported that 2 cases persisted and 3 cases resolved spontaneously).[8]

De novo prolapse

De novo rectocele incidence in patients treated by LSC was 12% (16/138) at the end of 8 years follow-up in the case series of 165 women. Cystocele rate was 8% (11/183) in women from the same study.[8]

Infection

Infection rates were not statistically significantly different in women treated by SCP using mesh (3% [17/676]) compared to patients treated by native tissue

repair 91% [9/617, (OR 2.01; 95% CI 0.91 to 4.45) in the analysis of comparative studies reported in the systematic review and meta-analysis of 1,176 women. Infection rates were not statistically significantly different between women treated by mesh SCP (2% [114/5,519] compared to the native tissue repair (12% [558/4,743], p=0.6) in in the analysis of non-comparative studies for the same systematic review.[2]

Abscess formation rate in patients treated by RASC was less than1% (3/1,118) in the systematic review and meta-analysis of 1,488 patients from 27 studies. Peritonitis caused by bowel injury happened in less than1% (2/1,118) patients in the same analysis.[3]

Fever in women treated by LSC was 6% (10/165) in the case series of 165 women.[8]

Bleeding

Bleeding rates were not statistically significantly different in women treated by SCP using mesh (3% [43/1,317]) compared to patients treated by native tissue repair (92% [37/1,863]) (OR 1.00; 95%CI 0.63 to1.59) in the comparative studies reported in the systematic review and meta-analysis of 1,176 women. Bleeding rates were statistically significantly lower in women treated by mesh SCP (2% [128/6,555]) when compared to the native tissue repair (5% [367/7,044], p<0.05) in the analysis of non-comparative studies for the same systematic review.[2] Vaginal haematoma in patients treated by LSC were reported in 1% (2/165) of patients in the case series of 165 women.[8]

Bowel obstruction

Ileus or bowel obstruction rates were statistically significantly higher in patients treated by SCP using mesh (2% [16/814]) than patients treated by native tissue repair (less than1% [2/780]), (OR 9.45 [3.39-26.4]) in the analysis of comparative studies reported in the systematic review and meta-analysis of 1,176 women. Ileus or small bowel obstruction was also statistically significantly higher in women treated by mesh SCP (3% [137/4,168]) compared with the native tissue repair (less than % [3/1,449], p<0.01) in in the analysis of non-comparative studies for the same systematic review.[2]

Bowel obstruction rate in women treated by RASC was less than1% (5/1,118) in the systematic review and meta-analysis of 1,488 patients from 27 studies.[3]

Bowel obstruction incidence in women treated by LSC was 1% (1/99) and 5% (4/85) at 12 and 60 months respectively, in the prospective case series of 101 women.[6]

Pain

Lumbosciatica pain was reported in 3% (5/165) of women treated by LSC in the case series of 165 women.[8]

Other

Port site hernia incidence in women treated by RASC was less than 1% (6/1,118), in the systematic review and meta-analysis of 1,488 patients from 27 studies. Vaginal cuff dehiscence occurred in 1 patient from the same systematic review. Intraoperative complication rate difference was not statistically significant when comparing RASC to LSC (OR 1.05; 95%CI 0.52 to 2.12 [n=443], I^2=0%, p=0.94) in a meta-analysis of this systematic review. Surgical conversion to open surgery was also not statistically significantly different when comparing the RASC and LSC treatment groups (OR: 0.89; 95%CI 0.25 to 3.19 [n=443], I^2=0%, p=0.72). The incidence of all grades post-operative complications was not statistically significant when comparing RASC to LSC (OR 1.85; 95%CI 0.96 to 3.75 [n=350], I^2=37%, p=0.18) and this was also true for severe post-operative complications (grade≥3) (OR 0.56; 95%CI 0.36 to 2.83 [n=430], I^2=24%, p=0.73).[3]

Validity and generalisability of the studies

- There is some heterogeneity between the study samples included in the analysis. This can partially be explained by the number of variations sacrocolpopexy has as a procedure. Multiple approaches such as open abdominal, laparoscopic and robotic can be used. The composition and weight of the mesh necessary for the treatment can also vary between studies.
- There are different surgeries that can be done concomitantly to sacrocolpopexy. It is not always possible to distinguish the immediate and long-term safety and efficacy outcomes related to sacrocolpopexy alone.
- There are 3 systematic reviews and meta-analysis included in the analysis that cover different approaches to sacrocolpopexy, different types of mesh and a

range of procedures done concomitantly.[1-3]The remaining papers in table 2 include 2 randomised control trials with maximum follow-up of 7 years[4] and 3 prospective case series with follow-ups between 4 and 6 years[5-8].

Existing assessments of this procedure

In December 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published an opinion on 'The safety of surgical meshes used in urogynaecological surgery'. It stated: The SCENIHR considers 3 factors as being important when assessing the risks associated with mesh application: the overall surface area of material used, the product design and the properties of the material used.' In addition, the available evidence suggests a higher morbidity in treating female pelvic organ prolapse (POP) than Stress Urinary Incontinence (SUI), as the former uses a much larger amount of mesh.[9]

The body of evidence suggests that when assessing the health risks of synthetic meshes, there is a need to clearly separate the smaller risks associated with stress urinary incontinence sling surgery from those of pelvic organ prolapse mesh surgery.[9]

Based on the currently marketed products, assessment of the risks reported indicates that polypropylene type 1 meshes are the most appropriate synthetic meshes for vaginal use and polypropylene type 1 and polyester type 3 for insertion via the abdominal route. However, there is a need for further improvement in the composition and design of synthetic meshes, in particular for female pelvic organ prolapse surgery."[9]

SCENIHR's recommendations include:• Material properties, product design, overall mesh size, route of implantation, patient characteristics, associated procedures (e.g. hysterectomy) and surgeon's experience are aspects

influencing the clinical outcome following mesh implantation. Such aspects are to be considered when choosing appropriate therapy.

• For all procedures, the amount of mesh should be limited where possible.

• The implantation of any mesh for the treatment of POP via the vaginal route should be only considered in complex cases in particular after failed primary repair surgery.

• A certification system for surgeons should be introduced based on existing international guidelines and established in cooperation with the relevant European Surgical Associations."[9]

A mesh working group interim report was published in December 2015 by NHS England. Its recommendations included: reviewing the current NICE guidance and creating new guidance, raising awareness amongst GPs of complications and how to address them, improving rates of reporting of adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA), and submissions to the British Society of Urogynaecology (BSUG) and British Association of Urological Surgeons (BAUS) databases, improving HES coding, raising awareness amongst patients of their option to use MHRA reporting procedures for adverse incidents, and developing information leaflets on mesh implant procedures for both stress urinary incontinence (SUI) and pelvic organ prolapse (POP) which provide consistent and understandable information to be used in the consenting process.[10]

In February 2016 the Royal College of Obstetricians and Gynaecologists (RCOG) published an addendum updating its guidance on the management of post-hysterectomy vaginal vault prolapse. The document states laparoscopic

sacrocolpopexy is as effective as abdominal sacrocolpopexy in the management of vaginal vault prolapse.[11]

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

- Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG283 (2009). Available from https://www.nice.org.uk/guidance/IPG283
- Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG284 (2009). Available from https://www.nice.org.uk/guidance/IPG284
- Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair. NICE Interventional procedure guidance IPG282 (2009). Available from https://www.nice.org.uk/guidance/IPG282
- Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG281 (2009). Available from https://www.nice.org.uk/guidance/IPG281
- Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG280 (2009). Available from https://www.nice.org.uk/guidance/IPG280
- Surgical repair of vaginal wall prolapse using mesh. NICE Interventional procedure guidance IPG267 (2008). Available from https://www.nice.org.uk/guidance/IPG267
- Single-incision sub-urethral short tape insertion for stress urinary incontinence in women. NICE Interventional procedure guidance IPG262 (2008). Available from https://www.nice.org.uk/guidance/IPG262h – being updated, to be published in November 2016

NICE guidelines

- Urinary incontinence in women (2013) NICE guideline CG171 (2013). Available from https://www.nice.org.uk/guidance/cg171

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Two Specialist Advisor Questionnaires for sacrocolpopexy using mesh for vaginal wall prolapse repair were submitted and can be found on the NICE website.

Patient commentators' opinions

Fourteen commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

Section to be inserted if there is no patient commentary

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Section to be inserted if patient commentators raised no new issues

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers.

Section to be inserted if patient commentators raised new issues

The patient commentators raised the following issues about the safety/efficacy of the procedure, which did not feature in the published evidence or the opinions of specialist advisers, and which the committee considered to be particularly relevant:

- [insert additional efficacy and safety issues raised by patient commentators and highlighted by IPAC, add extra rows as necessary].
- [Last item in list].

Company engagement

A structured information request was sent to 3 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Two of the systematic reviews and meta-analyses included in table 2 includes patients that had other procedures such as hysteropexy, cervicopexy and hysterectomy concomitantly to sacrocolpopexy. Subgroup analysis was not always available.
- NCT02676973: Apical Suspension Repair for Vault Prolapse in a Three-Arm Randomized Trial Design (ASPIRe). Study type: multi-center RCT; population: 363 women adult treated by sacral colpopexy compared with apical transvaginal mesh post hysterectomy; location: USA; study start date: March 2016; estimated completion date: February 202; estimated study completion date=April 202. Responsible party: National Institute of Child Health and Human Development Pelvic Floor Disorders Network.

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11. Royal College of Obstetricians and Gynaecologists, Post Hysterectomy vaginal Vault Prolapse (Green-top Guideline No.46) Addendum. Published February 2016. https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg46/

Appendix A: Additional papers on sacrocolpopexy using mesh for vaginal vault repair

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies. Given the large amount of evidence available on this procedure, non-randomised studies with less than 100 patients and follow-up less than 2 years were excluded from the analysis.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Barber MD, Maher C (2013) Apical prolapse. International Urogynecology Journal24:1815-1833.	Systematic review	Sacral colpopexy is an effective procedure for vault prolapse and further data are required on the route of performance and efficacy of this surgery for uterine prolapse. Polypropylene mesh is the preferred graft at ASC. Vaginal procedures for vault prolapse are well described and are suitable alternatives for those not suitable for sacral colpopexy.	Systematic review no meta-analysis. Non new safety events.
Bradley CS, Kenton KS, Richter HE et al. (2008) Obesity and outcomes after sacrocolpopexy. American journal of obstetrics and gynecology 199:1-8.	Prospective case series n=322 (74 obese, 122 overweight, 125 healthy weight) – in the original study FU=24 months	When compared to healthy weight women, obese women were younger, more likely to have stage 2 prolapse and had longer operative times. There was no difference in objective and subjective cure rates.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Chan SS, Pang SM, Cheung TH et al. (2011) Laparoscopic sacrocolpopexy for the treatment of vaginal vault prolapse: with or without robotic assistance. Hong Kong Medical Journal 17:54-60.	Retrospective case series n=36 (20 LSC versus 16 RASC) FU=29 months	Objective and subjective cure rates were similar in both groups. RASC was associated with longer hospital stay. There were no mesh erosions or exposure during follow-up.	Studies with more patients or longer follow-up are already included. Studies with more patients or longer follow-up are already included. No new safety events reported.
Claerhout F, De Ridder D , Roovers JP et al. (2008) Medium-term anatomic and functional results of laparoscopic sacrocolpopexy beyond the learning curve. European Urology 55:1459-67.	Prospective case series n=132 LSC FU=13 months	LSC demonstrated good objective and subjective cure rates. The posterior compartment was more vulnerable to prolapse at follow-up.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Culligan PJ, Gurshumov E, Lewis C et al. (2014) Subjective and objective results 1 year after robotic sacrocolpopexy using a lightweight Y-mesh. International Urogynecology Journal 25:731-5.	Prospective case series n=150 RASC with lightweight mesh FU=12 months	Good subjective and objective cure rates. No mesh erosions or exposures at follow-up.	Studies with more patients or longer follow-up are already included. Included in the paper by Serati 2014.

Culligan PJ, Salamon C, Priestley JL, et al. (2013) Porcine dermis compared with polypropylene mesh for laparoscopic sacrocolpopexy: a randomized controlled trial. Obstetrics & Gynecology 121:143-151.	RCT n=115 LSC (57 Porcine graft versus 58 polypropylene mesh) FU=12 months	Similar objective and subjective cure rates in both groups. No major operative complications.	Study included in the paper by Maher 2013.
Cundiff GW, Varner E, Visco AG et al. (2008) Risk factors for mesh/suture erosion following sacral colpopexy. American journal of obstetrics and gynecology 688:1-5.	Prospective case series n=322 (157 SCP with Burch colposuspension versus 165 SCP only) – In the original RCT FU=2 years	Polytrafluroethylene mesh was associated with higher rates of erosion and shouldn't be used for SCP. Concurrent hysterectomy and smoking are modifiable risk for mesh/suture erosion.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Deffieux X, Letouzey V, Savary D et al. (2012) Prevention of complications related to the use of prosthetic meshes in prolapse surgery: Guidelines for clinical practice. European Journal of Obstetrics Gynecology and Reproductive Biology 165:170-180.	Systematic review	The laparoscopic approach is recommended for sacral colpopexy (Expert opinion). It is recommended not to place and suture meshes by the vaginal route when a sacral colpopexy is performed (Grade B). It is recommended not to use silicone-coated polyester, porcine dermis, fascia lata, and polytetrafluoroethylene meshes (Grade B). It is recommended to use polyester (without silicone coating) or polypropylene meshes (Grade C). Suture of the meshes to the promontory can be performed using thread/needle or tacks (Grade C). Peritonization is recommended to cover the meshes (Grade C). If hysterectomy is required, it is recommended to perform a subtotal hysterectomy (Expert opinion). Implementation of this guideline should decrease the prevalence of complications related to surgical procedures involving the use of prosthetic meshes.	Systematic review with no meta-analysis. No mew safety events.

Deprest J, De Ridder D , Roovers JP et al. (2009) Medium-term anatomic and functional results of laparoscopic sacrocolpopexy beyond the learning curve. European Urology 55:1459-67.	Prospective case series n=150 (21 porcine grafts of small intestine submucosa, 29 dermal collagen versus 100 polypropylene mesh) FU=33 months	Overall anatomic failure was comparable. SCP using xenograft was associated with more apical failures and reoperations for prolapse than polypropylene.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Diwadkar GB, Barber MD, Feiner B (2009) Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. Obstetrics & Gynecology 113:367-373.	Systematic review.	The rate of complications requiring reoperation and the total reoperation rate was highest for vaginal mesh kits despite a lower reoperation rate for prolapse recurrence and shorter overall follow-up.	Systematic review with no meta-analysis. No new safety complications.
Filmar GA, Fisher HW, Aranda E et al. (2014) Laparoscopic uterosacral ligament suspension and sacral colpopexy: results and complications. International Urogynecology Journal 25:1645-1653.	Retrospective case series n=290 (102/290 stage 2 prolapse of which 73 LSC versus laparoscopic uterosacral ligament suspension) FU=112-114 days	There was no statistically significant difference in the rates of mesh erosion between concomitant total laparoscopic hysterectomy and prior hysterectomy. SCP resulted in statistically significant better anterior compartment support that uterosacral ligament suspension.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Ganatra AM, Rozet F, Sanchez-Salas R et al. (2009) The current status of laparoscopic sacrocolpopexy: a review. European Urology 55:1089-1103.	Systematic review	LSC upholds the outcomes of the gold standard ASC with minimal morbidity. Longer prospective and randomized trials are needed to confirm these results.	Systematic review with no meta-analysis. No new safety events reported.
Geller EJ, Parnell BA, Dunivan GC et al. (2012) Robotic vs abdominal sacrocolpopexy: 44-month pelvic floor outcomes. Urology 79:532-6.	Retrospective case series n=51 (23 RASC versus 28 SCP) FU=44 months	Objective and subjective success was similar in both groups. Mesh erosion rate was similar in both groups.	Studies with more patients or longer follow-up are already included. No new safety events reported.

Geller EJ, Siddiqui NY, Wu JM et al. (2008) Short-term outcomes of robotic sacrocolpopexy compared with abdominal sacrocolpopexy. Obstetrics & Gynecology112:1201-1206.	Retrospective case series n=178 (73 RASC versus 105 SCP) FU=6 weeks	RASC demonstrated similar short-term vaginal vault support compared with SCP, with longer operative time, less blood loss and shorter length of stay.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Galczynski K, Nowakowski L, Romanek-Piva K et al. (2014) Laparoscopic mesh procedures for the treatment of pelvic lorgan prolapse--review of the literature. Ginekologia Polska 85:950-954.	Literature review. .	Laparoscopic sacrocolpopexy hysteropexy and lateral suspension are interesting and effective options for the treatment of pelvic organ prolapse, providing a number of important advantages characteristic for endoscopic techniques.	Literature review no meta-analysis.
Ginath S, Garely AD, Condrea A et al (2013) Mesh erosion following abdominal sacral colpopexy in the absence and presence of the cervical stump. International Urogynecology Journal and Pelvic Floor Dysfunction 24:113-118.	Retrospective case series n=277 (195 SCP with concomitant supracervical hysterectomy versus 82 SCP with previous total hysterectomy) FU=7-8 months	Similar objective success rates. Operative times were similar in both groups. The total hysterectomy group had higher rate of mesh erosion but this was not statistically significant follow-up.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Hill A J, Barber MD (2015) Apical prolapse repair: weighing the risks and benefits. Current Opinion in Obstetrics & Gynecology 27:373-379.	Systematic review.	Surgical restoration of the vaginal apex can be accomplished via a variety of approaches and techniques. When deciding on the proper surgical intervention, the surgeon must carefully calculate the risks and benefits of each procedure while incorporating the patient's individual medical and surgical risk factors. Lastly, a discussion regarding the patient's overall goals of care is paramount to the decision-making process.	Systematic review with no meta-analysis. No new safety events.
Hudson CO, Northington GM, and Karp DR et al. (2012) Outcomes of robotic sacrocolpopexy: A systematic review and meta-analysis. Female pelvic medicine & reconstructive surgery 20: 252-260.	Systematic review and meta-analysis	RAASC is an effective surgical treatment for apical prolapse with high anatomic cure rate and low rate of complications.	Most of the reported studies overlap with papers analysed by Maher and Serati, both included in table 2. No new safety events reported.

Ivovic J, Kljakic D, and Raicevic (2012) Abdominal colposacropexy with permanent polypropylen mesh. Internet Journal of Gynecology and Obstetrics16:no pagination.	Prospective case series n=15 FU=9 months to 10 years	Satisfactory objective and subjective cure rates. No recurrence of prolapse, de novo urinary stress incontinence or dyspareunia.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Jeon MJ, Moon YJ, Jung HJ et al. (2009) A long-term treatment outcome of abdominal sacrocolpopexy. Yonsei Medical Journal 50:807-813.	Retrospective case series n=57 SCP FU=66 months	SCP had a reasonable objective cure rate for prolapse; nonetheless nearly half of the patients developed recurrent stress urinary incontinence within 1-3 months post-operatively. Bowel and sexual function did not significantly change after surgery. Major complications requiring reoperation or intensive care developed in one fifth of the patients. Two meshes were used: polytetrafluoroethylene and polypropylene. The author did not state how many patients had which type of mesh. Most severe complications happened in patients who had concomitant hysterectomy.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Jia X, Glazener C, Mowatt G (2010) Systematic review of the efficacy and safety of using mesh in surgery for uterine or vaginal vault prolapse. International Urogynecol Journal 21:1413-1431.	Systematic review	Sacrocolpopexy was associated with a low risk of recurrence but with a relatively high risk of mesh erosion. Ranges of estimates for outcomes for other mesh techniques were wide.	Systematic review no meta-analysis. No new safety events.
Khan A, Alperin M, Wu N et al. (2012) Comparative outcomes of open versus laparoscopic sacrocolpopexy among Medicare beneficiaries. International Urogynecology Journal 24:1883-1891.	Retrospective case series n=970 (794 SCP versus 176 LSC) FU=12 months	LSC was associated with significantly higher rate of reoperation for anterior vaginal wall prolapse. More medical complications (cardio-pulmonary) occurred post-operatively in the SCP group. When hysterectomy was done concomitantly, mesh related complications were significantly more frequent in the LSC group.	Studies with more patients or longer follow-up are already included. No new safety events reported.

Lamb SV, Massengill J, Sheridan MJ et al. (2015) Safety of combined abdominal sacral colpopexy and sigmoid resection with suture rectopexy: a retrospective cohort study. Female Pelvic Medicine & Reconstructive Surgery 21:18-24.	Retrospective case series n=194 (133 SCP, 34 SCP and sigmoid resection, 27 sigmoidectomy and rectopexy group) FU=12 months	The colorectal only group had a higher rate of ileus post-operatively. There were otherwise no differences in the rate of post-operative complications between groups. SCP using mesh at the time of sigmoid resection and anastomosis doesn't seem to increase the rate of post=operative complications.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Lee K, Mottrie A, Payne CK et al. (2014) A review of the current status of laparoscopic and robot-assisted sacrocolpopexy for pelvic organ prolapse. 65: 1128-1137.	Systematic review	LSC and RASC provide excellent short to medium term reconstructive outcomes for patients with POP. RASC is more expensive than LSC. Further studies are required to better understand the clinical performance of RASC versus LSC and confirm long-term efficacy.	Systematic review with no meta-analysis.
Leruth J, Fillet M, Waltregny D (2013) Incidence and risk factors of postoperative stress urinary incontinence following laparoscopic sacrocolpopexy in patients with negative preoperative prolapse reduction stress testing. International Urogynecology Journal and Pelvic Floor Dysfunction 24:485-491.	Retrospective case series n=55 LSC without concomitant SUI surgery after a negative preoperative prolapse reduction stress test FU=25 months	No patient developed recurrent prolapse or mesh erosion at follow-up. More than half of the patients reported symptoms of SUI postoperatively. Univariate analysis revealed that advanced cystocele (stage 3-4) and an history of patient-reported SUI before surgery were associated with higher risk of post-operative SUI after LSC. After 1 year follow-up, approximately one sixth of the patients underwent sling surgery.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Liang S, Zhu L, Song X et al. (2016) Long-term outcomes of modified laparoscopic sacrocolpopexy for advanced pelvic organ prolapse: a 3-year prospective study. Menopause 23:765-70.	Prospective case series n=30 modified LSC FU=3 years	Objective cure rates at 3 years follow-up were significant compared to baseline assessment. Sexual function was significantly improved. There was one case of mesh exposure and 2 cases of de novo dyspareunia.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Loffeld CJ, Thijs S, Mol BW et al. (2009) Laparoscopic sacrocolpopexy: a comparison of Prolene and Tutoplast mesh. Acta Obstetricia et Gynecologica Scandinavica 88:826-830.	Retrospective case series n=39 LSC (19 Tutoplast® versus 20 Prolene®) FU=45 months	There were no significant differences in operating time, blood loss or hospital stay between the groups. The risk of re-intervention because of prolapse was higher in the Tutoplast® group. Subjective cure rate was higher in the Prolene® group.	Studies with more patients or longer follow-up are already included. No new safety events reported.

Maher CF, Feiner B, DeCuyper EM et al. (2011) Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial. American Journal of Obstetrics & Gynecology 204: 1-7.	RCT N 108 (53 LSC versus 55 TVM) FU=24 months	At two years the LSC had a higher satisfaction rate and objective success rate than the total vaginal mesh with lower perioperative morbidity and reoperation rate.	Study included in the paper by Maher 2013 in table2.
Martin LA, Calixte R, Finamore PS (2015) Reoperation After Robotic and Vaginal Mesh Reconstructive Surgery: A Retrospective Cohort Study. Female Pelvic Medicine & Reconstructive Surgery 21:315-318.	Retrospective case series n=145 (181 RASC versus 64 transvaginal mesh repair) FU=RASC 3 months, TVM 12 months	TVM repair had shorter operation time. There was no significant difference in re-operation rate between the groups.	Studies with more patients or longer follow-up are already included. No new safety events reported.
McDermott CD, Park J, Terry CL et al. (2012) Surgical outcomes of abdominal versus laparoscopic sacral colpopexy related to body mass index.Journal of Obstetrics & Gynaecology Canada: JOGC 34:47-56.	Retrospective case series n=240 (90 SCP versus 150 LSC) FU=6-12 months	In normal weight patients, post-operative apical measurements were significantly worse in SCP patients. In overweight patients, the SCP group had significantly worse posterior measurements and fewer mesh erosions but more recurrent prolapse symptoms. In obese patients, the SCP group had significantly better anterior measurements. There was no significant difference between groups in regards to stage of prolapse, surgical satisfaction or surgical success or failure.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Mueller MG, Jacobs K M, Mueller ER et al. (2016) Outcomes in 450 Women After Minimally Invasive Abdominal Sacrocolpopexy for Pelvic Organ Prolapse. Female Pelvic Med Reconstr Surg 22:267-271.	Retrospective case series n=450 (232 SCP versus 226 RASC) FU=13 weeks	There were no significant differences between objective and subjective cure rates or bowel complications between the groups.	Studies with more patients or longer follow-up are already included. No new safety events reported.
North CE, Ali-Ross NS, Smith AR et al. (2009) A prospective study of laparoscopic sacrocolpopexy for the management of pelvic organ prolapse. BJOG: An International Journal of Obstetrics & Gynaecology 116:1251-7.	Retrospective case series n=22 LSC FU=27 months	Good rates of objective and subjective cure. Bowel symptoms were uncommon. Women have maintained sexual function with no dyspareunia.	Studies with more patients or longer follow-up are already included. No new safety events reported.

Porena M, Costantini E, Fioretti Fet al. (2009) The management of pelvic organ prolapse: a review. Minerva Urologica e Nefrologica 61:363-371.	Systematic review.	SCP seems to obtain better anatomic outcomes than sacrospinous fixation but has a longer operation time and patient morbidity.	Systematic review with no meta-analysis. No new safety events.
Quiroz LH, Gutman RE, Shippey S et al (2008) Abdominal sacrocolpopexy: anatomic outcomes and complications with Pelvicol, autologous and synthetic graft materials. American Journal of Obstetrics & Gynecology 198:1-5.	Retrospective case series n=259 LSC (102 Pelvicol ®, 134 synthetic mesh, 23 autologous fascia) FU=12 months	No statistically significant apical failure differences between groups. All reoperations occurred in the Pevicol® group. The Pevicol® groups had higher rates of mesh related complications but the difference wasn't statistically significant.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Rondini C, Braun H, Alvarez J et al. (2014) High uterosacral vault suspension vs Sacrocolpopexy for treating apical defects: a randomized controlled trial with twelve months follow-up. International Urogynecology Journal 26:1131-8.	RCT n=110 (54 SCP versus 56 high uterosacral vault suspension) FU=12 months	SCP has statistically better anatomical results when compared with HUVS for correcting apical defects at 12 months.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Salamon CG, Lewis C, Priestley J et al. (2013) Prospective study of an ultra-lightweight polypropylene Y mesh for robotic sacrocolpopexy. International Urogynecology Journal 24:1371-1375.	Prospective case series. n=120 RASC FU=12 months	Objective cure rates were satisfactory and subjective cure rates significant at follow-up. There were no mesh erosions or mesh related complication.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Sergent F, Resch B, Loisel C et al. (2011) Mid-term outcome of laparoscopic sacrocolpopexy with anterior and posterior polyester mesh for treatment of genito-urinary prolapse. European Journal of Obstetrics, Gynecology, and & Reproductive Biology 156:217-22.	Prospective case series. n=116 LSC FU=34 months	Anatomical success rates on the apical, anterior or posterior compartments were respectively, 97%, 89% and 98%. On the functional level all the scores of quality of life and sexuality were improved.	Some patients had concomitant hysterectomy alongside LSC and it wasn't possible to obtain sub-group analysis for the outcomes of interest of this synthesis.
Sierra JM , Oshiro EO, Perez CF et al. (2011) Long-term outcomes after robotic sacrocolpopexy in pelvic organ prolapse: prospective analysis. Urologia Internationalis 86:414-418.	Prospective case series n=31 RASC FU=25 months	There was 1 conversion to SCP. There were 2 major complications (1 acute myocardial infarction and 1 reoperation for excess tension with syncopes), two minor complications (1 wound infection and 1 ileus) and no recurrences at follow-up. Success of RASC might improve with experience. More evidence is required regarding safety of RASC.	Already included in the paper by Serati (2014).

Stanford EJ, Cassidenti A, Moen MD (2012) Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: providing an accurate interpretation of current literature. International Urogynecology Journal 23:19-28.	Systematic review.	There may be a higher rate of complications noted for mesh implantation. POP surgery is complex, and both NT and MA techniques require skills to perform proper compartmental reconstruction. An understanding of the published literature and knowledge of individual surgeon factors are important in deciding which surgical approach to use and how to best counsel patients during informed consent.	Systematic review no meta-analysis.
Tan-Kim J, Menefee SA, Lippmann Q et al. (2014) A pilot study comparing anatomic failure after sacrocolpopexy with absorbable or permanent sutures for vaginal mesh attachment. Permanente Journal 18:40-44.	Retrospective case series n=193 SCP (45 delayed absorbable sutures versus 148 permanent sutures) FU=43 weeks	Objective failure rates differences were not statistically significant for all compartments.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Thomas AZ, Giri SK, Cox AM et al. (2009) Long-term quality-of-life outcome after mesh sacrocolpopexy for vaginal vault prolapse. BJU International 104: 1676-1679.	Prospective case series n=21 SCP FU=52.2 months	Total PDFI scores were significantly better after SCP. All patients reported a significant improvement of symptoms in the POPDI category. CRADI subscale score showed no significant change after SCP. There was an improvement of urinary symptoms in the UDI subscale but this wasn't statistically significant. Analysis of score differences over time after SCP showed an insignificant decreasing slope. Suggestion of long-term stability of symptoms, improved sexual function and patient satisfaction.	Studies with more patients or longer follow-up are already included. No new safety events reported.

Unger CA, Paraiso MF, Jelovsek JE et al. (2014) Perioperative adverse events after minimally invasive abdominal sacrocolpopexy. American Journal of Obstetrics & Gynecology 211:1-8.	Retrospective case series n= 406 (249 LSC versus RASC 121) FU=7 months	RSC was significantly associated with higher intra-operative bladder injury rate, higher estimated blood loss and reoperation rate for pelvic organ prolapse compared with LSC. Concomitant rectopexy was significantly associated with a higher risk of transfusion, pelvic/abdominal abcess formation and osteomyelitis. Mesh erosion rate difference didn't reach statistical significance.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Wong V, Guzman-Rojas R, Shek KL et al. (2016) Laparoscopic sacrocolpopexy: how low does the mesh go? Ultrasound Obstet: DOI: 10.1002/uog.15882Gynecol	Retrospective case series n= 97 LSC FU=3 years	At follow-up there were no recurrences of apical prolapse but cystocele recurrence was common despite emphasis on anterior mesh extension. The author suggests that the lower the mesh reaches towards the bladder neck, the less likely will anterior compartment occur.	Studies with more patients or longer follow-up are already included. No new safety events reported.
Yurteri-Kaplan LA, Gutman RE (2012) The use of biological materials in urogynecologic reconstruction: a systematic review. Plastic & Reconstructive Surgery 130:242S-253S.	Systematic review	For prolapse surgery, the addition of a biological graft adds no benefit compared with native tissue repairs for rectocele repair. Conflicting data exist regarding cystocele repair. Synthetic mesh repairs provide superior anatomical support for sacral colpopexy and cystocele repair compared with biologic grafts. However, biological and synthetic mesh slings have equivalent success rates for the treatment of stress urinary incontinence. Contrary to prior assumptions that biologic grafts add tissue strength without graft-related complications, there appears to be no benefit to the use of biological materials for prolapse and incontinence surgery.	Systematic review with no meta-analysis. No new safety report.

Appendix B: Related NICE guidance for sacrocolpopexy using mesh for vaginal vault prolapse repair

Guidance	Recommendations

Interventional procedures	**Sacrocolpopexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG283 (2009).** It replaces the previous guidance on mesh sacrocolpopexy for vaginal vault prolapse (Interventional Procedures Guidance no. 215, March 2007). 1.1 Current evidence on the safety and efficacy of sacrocolpopexy using mesh for vaginal vault prolapse repair appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit. 1.2 During the consent process, clinicians should ensure patients understand that there is a risk of recurrence of vaginal vault prolapse after any prolapse repair procedure, and that there is also a risk of complications, including mesh erosion (for example, into the vagina), and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 Evidence on safety and efficacy outcomes is limited to 5 years. Evidence on outcomes beyond 5 years and on different types of mesh would be useful. Further research should include patientreported quality-of-life outcome measures using validated scales. **Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG284 (2009).** 1.1 Current evidence on the safety and efficacy of sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence.

1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database.

1.5 NICE encourages further research into sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Future research should address short- and long-term efficacy, erosion rates and patient-reported quality-of-life outcome measures using validated scales.

Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair. NICE Interventional procedure guidance IPG282 (2009).

1.1 Current evidence on the safety and efficacy of insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended.

1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence.

1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database.

1.5 NICE encourages further research into mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair and may review the procedure on publication of further evidence on different types of mesh. Future research should include short- and long-term efficacy, safety outcomes (such as mesh erosion in the long term), patient-reported quality-of-life outcomes using validated scales and subsequent successful pregnancy.

Infracoccygeal sacropexy using mesh for vaginal vault prolapse repair. NICE Interventional procedure guidance IPG281 (2009).

This guidance replaces the previous guidance on posterior infracoccygeal sacropexy for vaginal vault prolapse (Interventional Procedures Guidance no. 125, May 2005).

	1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for vaginal vault prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake infracoccygeal sacropexy using mesh for vaginal vault prolapse repair should take the following actions: • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence. 1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for vaginal vault prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes using validated scales. **Infracoccygeal sacropexy using mesh for uterine prolapse repair. NICE Interventional procedure guidance IPG280 (2009).** 1.1 Current evidence on the efficacy and safety of infracoccygeal sacropexy using mesh for uterine prolapse repair is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake infracoccygeal sacropexy using mesh for uterine prolapse repair should take the following actions: • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's safety, including mesh erosion (for example, into the vagina) and the risk of recurrence, and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. 1.3 The procedure should only be carried out by surgeons specialising in the management of pelvic organ prolapse and female urinary incontinence.

	1.4 The British Society for Urogynaecology runs a database on urogynaecological procedures, and clinicians should enter details about all patients undergoing this procedure onto this database. 1.5 NICE encourages further research into infracoccygeal sacropexy using mesh for uterine prolapse repair, and may review the procedure on publication of further evidence on different types of mesh. Clinicians are encouraged to collect long-term data on clinical outcomes and patient-reported quality-of-life outcomes using validated scales. **Surgical repair of vaginal wall prolapse using mesh. NICE Interventional procedure guidance IPG267 (2008).** 1.1 The evidence suggests that surgical repair of vaginal wall prolapse using mesh may be more efficacious than traditional surgical repair of vaginal wall prolapse without mesh. Both efficacy and safety vary with different types of mesh, and the data on efficacy in the long term are limited in quantity. There is a risk of complications that can cause significant morbidity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake surgical repair of vaginal wall prolapse using mesh should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand that there is uncertainty about the long-term results and there is a risk of complications, including sexual dysfunction and erosion into the vagina, which would require additional procedures. They should provide them with clear written information. In addition, the use of the Institute's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having surgical repair of vaginal wall prolapse using mesh (see section 3.1). 1.3 This is a technically challenging procedure that should only be carried out by gynaecologists with special expertise in the surgical management of pelvic organ prolapse. Specific training is required when trocar introducer systems are used for the insertion of mesh. 1.4 Further publication of safety and efficacy outcomes will be useful. Research should aim to address the performance of different methods of repair and different types of mesh. It should also include evidence about long-term outcomes and patient-reported outcomes, such as quality of life and sexual function. The Institute may review the procedure upon publication of further evidence. **Single-incision sub-urethral short tape insertion for stress urinary incontinence in women. NICE Interventional procedure guidance IPG262 (2008). Available from https://www.nice.org.uk/guidance/IPG262**

NICE guidelines	**Urinary incontinence in women (2013) NICE guideline CG171 (2013).** 1.10 Surgical approaches for SUI 1.10.1 When offering a surgical procedure discuss with the woman the risks and benefits of the different treatment options for SUI using the information in information to facilitate discussion of risks and benefits of treatments for women with stress urinary incontinence. **[new 2013]** 1.10.2 If conservative management for SUI has failed, offer: • synthetic mid-urethral tape (see recommendations 1.10.3–8), **or** • open colposuspension (see also recommendation 1.10.9), **or** • autologous rectus fascial sling (see also recommendation 1.10.10). **[new 2013]** **Synthetic tapes** 1.10.3 When offering a synthetic mid-urethral tape procedure, surgeons should: • use procedures and devices for which there is current high quality evidence of efficacy and safety[10] • only use a device that they have been trained to use (see recommendations in section 1.11) • use a device manufactured from type 1 macroporous polypropylene tape • consider using a tape coloured for high visibility, for ease of insertion and revision. **[new 2013]** 1.10.4 If women are offered a procedure involving the transobturator approach, make them aware of the lack of long-term outcome data. **[new 2013]** 1.10.5 Refer women to an alternative surgeon if their chosen procedure is not available from the consulting surgeon. **[new 2013]** 1.10.6 Use 'top-down' retropubic tape approach only as part of a clinical trial. **[new 2013]** 1.10.7 Refer to single-incision sub-urethral short tape insertion for stress urinary incontinence (NICE interventional procedure guidance 262) for guidance on single-incision procedures. **[new 2013]** 1.10.8 Offer a follow-up appointment (including vaginal examination to exclude erosion) within 6 months to all women who have had continence surgery. **[new 2013]** **Colposuspension** 1.10.9 Do not offer laparoscopic colposuspension as a routine procedure for the treatment of stress UI in women. Only an experienced laparoscopic surgeon working in an MDT with expertise in the assessment and treatment of UI should perform the procedure. **[2006]** **Biological slings** 1.10.10 Do not offer anterior colporrhaphy, needle suspensions, paravaginal defect repair and the Marshall–Marchetti–Krantz procedure for the treatment of stress UI. **[2006]**

	Intramural bulking agents 1.10.11 Consider intramural bulking agents (silicone, carbon-coated zirconium beads or hyaluronic acid/dextran copolymer) for the management of stress UI if conservative management has failed. Women should be made aware that: • repeat injections may be needed to achieve efficacy • efficacy diminishes with time • efficacy is inferior to that of synthetic tapes or autologous rectus fascial slings. **[2006, amended 2013]** 1.10.12 Do not offer autologous fat and polytetrafluoroethylene used as intramural bulking agents for the treatment of stress UI. **[2006]** **Artificial urinary sphincter** 1.10.13 In view of the associated morbidity, the use of an artificial urinary sphincter should be considered for the management of stress UI in women only if previous surgery has failed. Life-long follow-up is recommended. **[2006]** **Considerations following unsuccessful invasive SUI procedures or recurrence of symptoms** 1.10.14 Women whose primary surgical procedure for SUI has failed (including women whose symptoms have returned) should be: • referred to tertiary care for assessment (such as repeat urodynamic testing including additional tests such as imaging and urethral function studies) and discussion of treatment options by the MDT, **or** • offered advice as described in recommendation 1.6.9 if the woman does not want continued invasive SUI procedures. **[new 2013**

Appendix C: Literature search for sacrocolpopexy using mesh for vaginal vault prolapse repair

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane)	06/06/2016	Issue 6 of 12, June 2016
HTA database (Cochrane)	06/06/2016	Issue 2 of 4, April 2016
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane)	06/06/2016	Issue 5 of 12, May 2016
MEDLINE (Ovid)	06/06/2016	1946 to May Week 4 2016
MEDLINE In-Process (Ovid)	06/06/2016	June 03, 2016
EMBASE (Ovid)	08/06/2016	1974 to 2016 Week 23
PubMed	06/06/2016	n/a
BLIC (British Library)	06/06/2016	n/a

Trial sources searched on 09 06 2016

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched on 09 06 2016

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 pelvic organ prolapse/

2 POP.ti,ab.

3 Uterine Prolapse/

4 vagina/

5 fascia/

6 ((apical* or post-hysterect* or cuff* or fascia* or pelvic* or cervic* or transvagin* or vagin* or genital* or uter* or urogenit* or womb* or genito* or intravaginal*) adj2 (prolaps* or collaps* or drop*)).ti,ab.

7 rectocele/

8 cystocele/

9 (rectocele* or cystocele* or enterocele*).ti,ab.

10 or/1-9

11 surgical mesh/

12 mesh*.ti,ab.

13 (biologic* adj4 (graft* or plast* or sling* or tape* or suspens* or gauze*)).ti,ab.

14 *Polypropylenes/ or *Polyglactin 910/

15 ((Polypropylene* or Polyglactin* or Novasilk* or Restonelle* or prolene* or trelex* or avaulta* or pelvitex* or prolift* or polyform* or marlex* or gynemesh* or gore* or vicryl* or tutoplast* or faslata* or fortagen* or porcine dermis* or pelvicol* or pelvisoft* or upsylon* or Elevate PC or bovine pericardium) adj2 (mesh* or graft* or plast* or sling* or tape* or suspens* or gauze*)).ti,ab.

16 or/11-15

17 10 and 16

18 *gynecologic surgical procedures/

19 suburethral slings/

20 urogential surgical procedures/ or urologic surgical procedures/

21 (Colporrhaph* or colpoperineorraph* or cystopex* or sacrohysteropex* or sacrocolpopex* or sacropex*).ti,ab.

22 or/18-21

23 17 and 22

24 (artisyn Y-shaped or inte-pro Y or uplift or prolife or perigee or apogee or elevate or capio or avaulta or i-stitch or restorelle or uphold LITE).ti,ab.

25 10 and 24

26 23 or 25

27 animals/ not humans/

28 26 not 27

29 limit 28 to ed=20070701-20160630